EXHIBIT A

Attorney Docket No. 16355-24
Client Reference No. 95003-2

PATENT APPLICATION

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND THEIR DELIVERY

Inventors:

Julian Nikolchev, a citizen of
The United States, residing at
251 Durazno Way,
Portola Valley, California 94028;

Dai Ton, a citizen of
The United States, residing at
1693 Flickinger Avenue,
San Jose, California 95131; and

Amy Thurmond, a citizen of
The United States, residing at
12031 So. West Breyman Avenue,
Portland, Oregon 97219.

Assignee:

CONCEPTUS, INC.
1021 Howard Avenue
San Carlos, California 94070,
a California corporation.

Status:

SMALL ENTITY

TOWNSEND and TOWNSEND KHOURIE and CREW
Steuart Street Tower, 20th Floor
One Market Plaza
San Francisco, California 94105
(415) 326-2400

PATENT
Attorney Docket No. 16355-24

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND THEIR DELIVERY

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to contraception, and more particularly to intrafallopian contraceptive devices and nonsurgical methods for their delivery.

Worldwide demand exists for safe, effective methods of both contraception and permanent sterilization. Although a variety of contraception and sterilization methods are available, all of the existing methods have limitations and disadvantages. Thus, the need for additional safe, low cost, reliable methods of contraception and permanent sterilization, both in developed and less developed countries, is widely recognized.

Many presently available contraception methods require significant user involvement, and user non-compliance results in quite high rates of failure. While the theoretical effectiveness of existing contraceptives, including barrier methods and hormonal therapies, is well established, overcoming user noncompliance to improve overall efficacy has proven difficult.

One form of contraception which is less susceptible to user noncompliance is the intrauterine device (IUD). IUDs have been found to have higher rates of reliability, and are effective for a longer period of time, than most other commercially available contraceptives. Unfortunately, IUDs are also associated with serious infectious complications. For this reason, the use of IUDs within the United States has decreased dramatically. Additionally, IUDs are subject to unplanned expulsion, and must be removed due to excessive pain or bleeding in a percentage of cases, further reducing the acceptance of the IUD as a contraceptive method.

Interestingly, the efficacy of copper IUDs appears to be higher than that of non-metallic IUDs. The reason for this has not been fully explained.

Commercially available options for permanent sterilization include fallopian tube ligation and vasectomy. These methods are surgical, are difficult to reverse, and are not available to many people in the world. It is common knowledge that fertilization occurs in the fallopian tubes where the sperm and ovum meet. Tubal ligation avoids this by complete occlusion of the fallopian tubes.

It has previously been proposed to reversibly occlude the fallopian tubes, for example, by *in vitro* formation of an elastomeric plug, or otherwise anchoring a device on either side of the narrowest region of fallopian tube, called the "isthmus." Such fallopian tube occlusion methods appear promising; however, an unacceptably high percentage of the non-surgical devices proposed to date have become dislodged during previous studies. Even where non-surgical intrafallopian devices have remained in place, they have been found to be only moderately effective at preventing conception.

For these reasons, it would be desirable to provide effective, reliable intrafallopian devices for contraception and sterilization. It would be particularly desirable to provide highly effective intrafallopian devices which did not require surgery for placement. It would be especially desirable if such devices and methods allowed easy placement of the device, but were less susceptible to being dislodged than previously proposed non-surgical intrafallopian devices.

2. Description of the Related Art

The experimental use of a stainless steel intrafallopian device is described in *Transcatheter Tubal Sterilization in Rabbits*, Penny L. Ross, RT 29 "Investigative Radiology", pp. 570-573 (1994). The experimental use of an electrolytically pure copper wire as a surgical contraceptive intrafallopian device in rats was described in "Antifertility Effect of an Intrafallopian Tubal Copper Device", D.N. Gupta,

14 *Indian Journal of Experimental Biology*, pp. 316-319 (May 1976).

U.K. Patent Application Pub. No. 2,211,095 describes a uterine screw plug for blocking the fallopian tube. European Patent Application Pub. No. 0,010,812 describes a device for placement in the oviducts having enlargements at either end for anchoring the device. The same device appears to be described in Netherlands Patent No. 7,810,696.

The use of tubal occlusion devices is described in "Hysteroscopic Oviduct Blocking With Formed-in-Place Silicone Rubber Plugs", Robert A. Erb, Ph.D., et al., *The Journal of Reproductive Medicine*, pp. 65-68 (August 1979). A formed-in-place elastomeric tubal occlusion device is described in U.S. Patent No. 3,805,767, issued to Erb. U.S. Patent No. 5,065,751, issued to Wolf, describes a method and apparatus for reversibly occluding a biological tube. U.S. Patent No. 4,612,924, issued to Cimber, describes an intrauterine contraceptive device which seals the mouths of the fallopian tubes.

German Patent No. 28 03 685, issued to Brundin, describes a device for plugging a body duct with a device which swells when in contact with a body fluid.

Alternative contraceptive devices are disclosed in copending U.S. Patent Application Serial No. _____ (attorney docket no. 16355-25), the full disclosure of which is herein incorporated by reference.

SUMMARY OF THE INVENTION

The present invention provides intrafallopian devices and methods for their placement to prevent conception. The intrafallopian devices of the present invention are transcervically delivered, resiliently anchored structures which are formed at least in part from copper to provide long term contraception, or alternatively permanent sterilization, without the need for surgical procedures or the increased bleeding, pain, and risks of infection associated with intrauterine devices (IUDs).

The use of copper in the intrafallopian device of the present invention improves its efficacy as a contraceptive method. Devices formed from plastically deformable materials, however, are less readily restrained in the fallopian tube. Apparently, the large variation in the actual shape and dimensions of fallopian tubes does not provide reliable anchoring for a pre-formed deformable intrafallopian device. The intrafallopian device of the present invention therefore comprises a resilient structure, usually a metallic coil, which includes a copper alloy, a copper plating, or copper fibers, ideally comprising an alloy including at least 75% copper. The coil material typically includes beryllium, zinc, stainless steel, platinum, a shape memory alloy such as Nitinol™, or the like. Preferably, the coil is composed of an alloy of beryllium and copper. Although the present device will generally result in occlusion, it need not completely occlude the fallopian tube to prevent the meeting of the sperm and ovum. Instead, the presence of the copper on the resilient structure is sufficient to provide effective contraception.

Conveniently, the present invention further comprises non-surgical placement of such intrafallopian devices by transcervical introduction. The resilient structure is restrainable in a straight configuration, e.g., by inserting the device within a catheter, greatly facilitating and reducing the risks of introduction. Thus, the cost and dangers associated with existing surgical contraceptive and sterilization procedures are avoided.

In a first aspect, a contraceptive intrafallopian device according to the present invention comprises a resilient structure having a proximal end and a distal end. The resilient structure comprises copper, and is biased to form at least one bend near the proximal end of the primary coil. Similarly, the resilient structure is also biased to form at least one bend near its distal end. These proximal and distal bends define an isthmus-traversing region therebetween. Preferably, the isthmus-traversing region also

includes at least one bend, thereby helping to anchor the coil within the fallopian tube.

Generally, the resilient structure of the present intrafallopian device will be formed as a primary coil. To help restrain the coil within the fallopian tube, fibers are attached to some embodiments of the coil, the fibers optionally comprising a polyester material such as Rayon™, Dacron™, or the like. Alternatively, copper fibers may be used to increase the exposed copper surface area, the copper fibers generally having a diameter on the order of .001 inches.

The bends of the present intrafallopian device are generally formed as a secondary shape imposed on a primary coil. The primary coil is most easily formed as a straight cylindrical coil. The secondary shape will be imposed on the primary coil by bending, optionally heat treating the primary coil while bent. The individual bends may take a wide variety of forms, including sinusoidal curves, the individual loops of a continuous secondary coil, or the like. However, the secondary shape generally defines an overall width which is larger than the fallopian tube, so that the tubal wall restrains the resilient structure when it is released.

Preferably, each of the bends of the present intrafallopian device forms a loop in the primary coil when in a relaxed state. Ideally, the loops are separated by straight sections of coil. The alternating of loops with straight sections of coil forms a large diameter "flower coil," which provides a large relaxed overall width, and also features bends of tight radius, both of which promote retention. Conveniently, the primary coil generally has a diameter less than that of the fallopian tube, and can be restrained in a straight configuration for placement within the fallopian tube, typically by inserting the primary coil within a delivery catheter.

In another aspect, a contraceptive intrafallopian device according to the present invention comprises a resilient primary coil having a primary coil diameter. The primary coil comprises copper, and forms a secondary shape

when in a relaxed state. The secondary shape defines a plurality of bends and an overall width which is larger than the primary coil diameter. Thus the primary coil can be easily anchored in a fallopian tube which is smaller in diameter than the secondary shape. Preferably, the present device reacts with a force sufficient to prevent axial movement of the device within the fallopian tube when restrained in a lumen having a diameter in the range between .5 mm and 3 mm. The actual anchoring force will depend on the shape of the coil and the modulus of elasticity of the material used.

In yet another aspect, a intrafallopian contraceptive delivery system according to the present invention comprises an elongate body in which the resilient primary coil described above is slidably disposed. A shaft is also slidably disposed within the elongate body and is located proximally of the primary coil. The distal end of the shaft includes a coil interface surface, while the elongate body restrains the primary coil in a straight configuration.

Preferably, a bend in the isthmus-traversing region of the present intrafallopian device, together with the proximal and distal anchor bends, restrains the resilient structure within the isthmus of the fallopian tube. The distal anchor is inserted into the ampulla, distal of the isthmus, while the proximal anchor is located in the ostium, proximal of the isthmus. Unintended movement of the device is further avoided by locating the isthmus-traversing region within the isthmus to resiliently impose anchoring forces against the tubal wall.

In a still further aspect, an intrafallopian contraceptive method according to the principles of the present invention comprises restraining a resilient structure in a straight configuration and transcervically inserting the resilient structure into a fallopian tube. The resilient structure is affixed within the isthmus by releasing a bent isthmus-traversing region. The bend of the isthmus-traversing region exerts a force against the wall of the fallopian tube, anchoring the device within the isthmus. Preferably, a distal

anchor on the resilient structure is released distally of the isthmus, and a proximal anchor is released proximally of the isthmus, the distal and proximal anchors generally formed from bends in the resilient structure. Optionally, an electric current is applied through the resilient structure to the fallopian tube, thereby effecting permanent sterilization.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a first embodiment of a contraceptive intrafallopian device according to the present invention having a single distal anchor loop, a single proximal anchor loop, and an isthmus-traversing region having a single loop for anchoring the device within the fallopian tube.

Fig. 2 illustrates an alternative embodiment of a contraceptive intrafallopian device according to the present invention having a plurality of loops which may act as proximal, distal, or lumen anchors.

Fig. 3 illustrates the distal portion of a delivery catheter for placement of a contraceptive intrafallopian device according to the present invention.

Fig. 4 illustrates the contraceptive intrafallopian device of Fig. 1 partially released from the delivery catheter of Fig. 3.

Figs. 5 and 6 illustrate a contraceptive method using an intrafallopian device according to the principles of the present invention.

DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENT

The present invention encompasses a contraceptive intrafallopian device which can alternatively be used as both a permanent and a reversible means of contraception. The present contraceptive methods and devices minimize the danger of non-use which has limited the efficacy of prior art contraceptive techniques. Moreover, the location of the present devices within the fallopian tubes provides a reduced risk of the infectious complications, increased bleeding, and pelvic pain associated with intrauterine devices (IUDs).

Furthermore, the location and the novel shape of the present intrafallopian device provides significant advantages over IUDs, which have been found to be susceptible to unplanned expulsion and removal due to excessive pain and bleeding. The present invention takes advantage of the increase in effectiveness associated with copper IUDs, providing a resilient structure including copper which may be transcervically positioned without the need for surgery.

Although the present contraceptive method may be included within a group of contraceptive techniques generally referred to as fallopian tube occlusion methods, the present invention does not necessarily rely solely on blocking the fallopian tube to prevent fertilization. Instead, contraception is apparently provided by disrupting of ovum transport, the process of fertilization, and/or cleavage of the ovum. While the effect that copper has on these processes is not fully understood, it does appear that copper intrafallopian devices offer potentially significant increases in effectiveness over intrafallopian devices formed of other materials. Optionally, the present invention further encompasses devices which promote tissue growth within the tube to induce tubal occlusion, further inhibiting conception.

The present invention is anchored within the isthmus of the fallopian tube, overcoming the unintended expulsion of the device and the resulting failure of the contraceptive method. Such intrafallopian device expulsion has been the single greatest factor limiting the efficacy of easily positioned intrafallopian contraceptive techniques.

The present intrafallopian devices are generally elongate resilient structures pre-formed into secondary shapes. These secondary shapes will bias the resilient structure so as to provide strong forces against the lumen wall of the fallopian tube. Clearly, the secondary shape must have a larger outer diameter than the inner diameter of the fallopian tube.

Conveniently, the present resilient structures are insertable into a catheter, the catheter wall restraining the resilient structure in a straight configuration. As the

resilient structure has an outer diameter when in the straight configuration which is less than the inner diameter of the fallopian tube, the catheter containing the present intrafallopian device is easily transcervically introduced. Moreover, the device is readily removed by snaring the resilient structure near the proximal end and pulling proximally on the resilient structure, thereby straightening the resilient structure and allowing it to be withdrawn without injuring the fallopian tube. Alternatively, an electrical current is applied to the device after it is at least partially releasing the fallopian tube, providing permanent sterilization.

Referring now to Fig. 1, a first embodiment of the present contraceptive intrafallopian device 10 is formed from a resilient primary coil 12. Primary coil 12 is most easily originally formed as a straight cylindrical coil or spring, preferably having an outer diameter in the range from .2 mm to 5 mm, and having a length in the range from 20 mm to 150 mm. Ideally, primary coil 12 has an outer diameter in the range from .4 mm to 2 mm and a length in the range from 30 mm to 70 mm. The straight primary coil may then be bent into a variety of secondary shapes.

The primary coil 12 of intrafallopian device 10 includes a proximal end 14 and a distal end 16. Between these ends, three loops 20 are formed, each having an inner diameter 22. Located between loops 20 are straight sections 24, which increase the overall cross-section of the intrafallopian device to an overall width 26. Preferably, inner diameter 22 is in the range from 2 mm to 10 mm, while overall width 26 is at least 6mm, ideally being in the range from 8 mm to 40 mm. Distal and proximal ends 14, 16 each include an atraumatic endcap 18 to prevent injury to the fallopian tube.

Preferably, primary coil 12 is formed from a beryllium copper alloy wire. Beryllium copper provides the resilience necessary to avoid expulsion of the device, and also provides the increased effectiveness of a copper contraceptive intrafallopian device. Alternatively, primary

coil 12 is formed from a resilient metal, such as stainless steel, platinum, a shape memory alloy, or the like. If such materials are used, primary coil 12 is preferably plated with copper or a copper alloy or otherwise has copper attached.

To further reduce the possibility of expulsion of intrafallopian device 10, fibers are optionally carried on primary coil 12. The fibers may be short individual fibers, or may alternatively be wound into primary coil 12. Preferably, the fibers comprise copper, thereby increasing the total copper surface area. Such copper fibers are preferably bonded to primary coil 12 with solder, brazing, a polymeric adhesive, or the like. Alternatively, polyester fibers such as Dacron™, Rayon™, or the like, are bonded to the surface of primary coil 12 using a polymeric adhesive. The polyester fibers promote increased tissue growth around the coil, thus further reducing the possibility of expulsion of the device from the fallopian tube.

A secondary shape has been superimposed on the primary coil to form intrafallopian device 10, the secondary shape comprising loops 20 separated by straight sections 24. This secondary shape is herein referred to as a "flower coil." The flower coil shape is particularly advantageous in that outer diameter 26 is substantially larger than the primary coil diameter, while the individual loops 20 have relatively small inner diameters 22 which will maintain the largest possible anchoring force against the fallopian tube. Minimizing inner diameter 22 also ensures that anchoring force is applied within the fallopian tube, despite the curvature of the fallopian tube.

Referring now to Fig. 2, an alternative embodiment of the present contraceptive intrafallopian device 30 includes additional loops to ensure anchoring of the device within the fallopian tube. Alternative embodiment 30 is formed from an elongate primary coil 32 having a proximal end 34 and a distal end (not shown). Elongate primary coil 32 has an outer diameter 36 which is smaller than the isthmus of the fallopian tube, allowing the straightened intrafallopian device to be inserted easily. Elongate primary coil 32 has been bent to

form a secondary shape including a larger number of loops 38 than the embodiment of Fig. 1. Loops 38 have an outer diameter 40 which is larger than the inner diameter of the fallopian tube, preventing loops 38 from assuming their relaxed shape. Loops 38 are again separated by straight sections 42 of elongate primary coil 32, increasing the overall intrafallopian device diameter 44.

In both embodiments of the present intrafallopian device 10, 30, at least one loop adjacent to the proximal end is disposed proximally of the narrowest portion of the fallopian tube, referred to as the isthmus. Similarly, at least one loop of the intrafallopian device is disposed distally of the isthmus. These proximal and distal loops act as anchors, helping to prevent proximal or distal movement of the intrafallopian device. In the embodiment of Fig. 2, at least one loop is also disposed adjacent to the isthmus of the fallopian tube, further helping to prevent unintentional expulsion.

Alternative intrafallopian device 30 may be positioned with multiple loops acting as proximal or distal anchors, or may alternatively have all but the proximal and distal anchor loops disposed along the fallopian tube to act as anchors within the lumen of that body. Advantageously, the embodiment of Fig. 2 is therefore less sensitive to variations in total fallopian tube length.

Referring now to Fig. 3, a delivery catheter for the present intrafallopian device comprises an elongate body 52 and a shaft 54. Elongate body 52 includes a lumen 56 in which shaft 54 is disposed, shaft 54 being slidable in the axial direction. Shaft 54 includes a core 58 having a tapered distal end 60, allowing the device to navigate through tortuous bends while retaining the column strength required to advance the device. Core 58 extends proximally through elongate body 52, and is capable of transferring compressive forces through the elongate body. Core 58 is typically formed from stainless steel, a stainless alloy, or the like. Disposed over distal end 60 of core 58 is pusher cap 62. Pusher cap 62 provides a low friction, deformable end piece

having a distal coil interface surface 64. Pusher cap 62 is preferably formed of a low friction polymer such as PTFE, or the like.

Intrafallopian delivery catheter 50 receives the present intrafallopian device within the distal end of lumen 56 of elongate body 52. Lumen 56 has an inner diameter which is slightly larger than outer diameter 36 of the primary coil. The present intrafallopian device is therefore straightened to a straight configuration as it is loaded proximally into the distal end of lumen 56. Elongate body 52 is sufficiently strong to restrain the primary coil in the straight configuration, but must remain sufficiently flexible to allow maneuvering within the body lumen. Elongate body 52 is preferably formed from an inelastic, flexible material such as polyurethane, PET, or the like.

Referring now to Fig. 4, intrafallopian device 10 is released from delivery catheter 50 within the fallopian tube by holding shaft 54 while proximally withdrawing elongate body 52. Distal coil interface surface 64 engages the proximal end 14 of primary coil 12. Initially, primary coil 12 is restrained in a straight configuration by elongate body 52. As elongate body 52 is withdrawn, primary coil 12 is released. When primary coil 12 is unrestrained it forms loop 20; when released within the fallopian tube it will generally be restrained by the tubal wall in a configuration between straight and the relaxed secondary shape. Preferably, the first loop released will form a distal anchor bend 66. Subsequent loops will bias primary coil 12 against the fallopian tube, and form a proximal anchor bend, in that order.

Use of the present contraceptive intrafallopian device will be described with reference to Figs. 5 and 6. A uterine introducer canula 70 is inserted transcervically through a uterus 72 to the region of an ostium 74. Elongate body 52 is then extended distally from canula 70 into a fallopian tube 77, preferably guided under fluoroscopy. Alternatively, a hysteroscope may be used in place of

canula 70. Elongate body 52 is maneuvered using a guide wire 78 past an isthmus 80.

After elongate body 52 extends past isthmus 80, guide wire 78 is removed. An intrafallopian device according to the present invention is inserted in the proximal end of elongate body 52, the intrafallopian device being restrained in a straight configuration by the elongate body. The device is advanced distally using shaft 54, the shaft and elongate body forming delivery catheter 50 (Fig. 3). Delivery catheter 50 is axially positioned so that at least one loop of the intrafallopian device is within a target region 84 adjacent to isthmus 80. Preferably, at least one loop is distal of target region 84, and at least one loop is proximal of target region 84 to form the distal and proximal anchor bends of the implanted intrafallopian device.

Once delivery catheter 50 is properly positioned, elongate body 52 may be axially withdrawn. Shaft 54 axially restrains the intrafallopian device at the target location during withdrawal of elongate body 52, as described regarding Fig. 4. As the distal end of the primary coil is released, the distal loop forms a distal anchor bend 90. Similarly, the proximal loop forms a proximal anchor bend 92. Intermediate loops are restrained within the narrow target region 84, exerting substantial anchoring forces against the walls of the fallopian tube. As seen in Fig. 6, the loops need not assume their relaxed form to provide effective distal or proximal anchors.

The present invention further encompasses permanent sterilization by passing a current through the shaft to the intrafallopian device after elongate body 52 has been partially withdrawn, but before the intrafallopian device is fully released. Fallopian tube tissue in contact with the intrafallopian device is dessechated, and thus attached to the present intrafallopian device. This action also causes permanent tubal damage, leading to the formation of scar tissue which encapsulates the intrafallopian device and causes permanent occlusion of the tubal lumen. Clearly, the

resilient member/shaft interface must be conductive to allow the present non-surgical method of permanent sterilization.

In conclusion, the present invention provides a contraceptive intrafallopian device which may be positioned without surgery. While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. For example, a wide variety of secondary shapes, including open loops, continuous bends, sinusoidal curves, or the like, may be imposed on the primary coil. Therefore, the above description should not be taken as limiting the scope of the invention, which is defined instead solely by the appended claims.

WHAT IS CLAIMED IS:

1. An intrafallopian contraceptive device comprising:

a resilient structure having a proximal end and a distal end, the resilient structure comprising copper and being biased to form at least one proximal anchor adjacent the proximal end and at least one distal anchor adjacent the distal end, the at least one proximal anchor and at least one distal anchor defining an isthmus-traversing region therebetween.

2. An intrafallopian contraceptive device as claimed in claim 1, wherein the resilient structure comprises a primary coil.

3. An intrafallopian contraceptive device as claimed in claim 2, wherein the primary coil comprises a material selected from the group consisting of beryllium, zinc, stainless steel, platinum, and shape memory alloy.

4. An intrafallopian contraceptive device as claimed in claim 3, wherein the primary coil comprises an alloy including beryllium and copper.

5. An intrafallopian contraceptive device as claimed in claim 2, wherein the primary coil comprises an alloy including at least 75% copper.

6. An intrafallopian contraceptive device as claimed in claim 3, wherein the primary coil comprises a plated layer of a material selected from the group containing copper and copper alloy.

7. An intrafallopian contraceptive device as claimed in claim 1, wherein the isthmus-traversing region includes one of the plurality of bends.

8. An intrafallopian contraceptive device as claimed in claim 1, further comprising fibers carried on the resilient structure, the fibers comprising a material selected from the group containing copper and polyester.

9. An intrafallopian contraceptive device as claimed in claim 1, wherein the resilient structure is restrainable in a straight configuration.

10. An intrafallopian contraceptive device as claimed in claim 9, wherein the resilient structure has an outer diameter in the range between .2 mm and 5 mm and a length in the range between 20 mm and 150 mm when in the straight configuration.

11. An intrafallopian contraceptive device as claimed in claim 9, wherein the resilient structure has a width of at least 3 mm when in a relaxed state.

12. An intrafallopian contraceptive device as claimed in claim 1, wherein the device comprises at least three bends which form loops in the resilient structure when in a relaxed state.

13. An intrafallopian contraceptive device as claimed in claim 12, wherein the loops are separated by straight sections when in a relaxed state.

14. An intrafallopian contraceptive device comprising:

a resilient primary coil having a proximal end, a distal end, and a primary coil diameter, wherein:

1) the primary coil comprises copper; and

2) the primary coil forms a secondary shape when in a relaxed state, the secondary shape defining a plurality of bends and an overall width which is larger than the primary coil diameter.

15. An intrafallopian contraceptive device as claimed in claim 14, wherein the primary coil comprises a material selected from the group consisting of beryllium, zinc, stainless steel, platinum, and shape memory alloy.

16. An intrafallopian contraceptive device as claimed in claim 14, wherein the coil comprises an alloy including beryllium and copper.

17. An intrafallopian contraceptive device as claimed in claim 14, further comprising fibers disposed on the resilient structure, the fibers comprising a material selected from the group containing copper and polyester.

18. An intrafallopian contraceptive device as claimed in claim 14, wherein the coil diameter is in the range between .2 mm and 5 mm.

19. An intrafallopian contraceptive device as claimed in claim 14, wherein the primary coil has a length in the range between 20 mm and 150 mm when in a straight configuration.

20. An intrafallopian contraceptive device as claimed in claim 14, wherein the overall width is at least 6 mm.

21. An intrafallopian contraceptive device as claimed in claim 14, wherein each of the bends forms a loop in the primary coil.

22. An intrafallopian contraceptive device as claimed in claim 21, wherein the loops are separated by straight sections.

24. An intrafallopian contraceptive delivery system comprising:

an elongate body having a proximal end, a distal end, and a delivery lumen;

a resilient primary coil slidably disposed within the elongate body, the primary coil having a proximal end and a distal end, the primary coil comprising copper and being biased to form at least one proximal anchor bend at the proximal end and at least one distal anchor bend at the distal end, the proximal and distal anchor bends defining an isthmus-traversing region therebetween;

a shaft slidably disposed within the delivery lumen of the elongate body proximally of the primary coil, the shaft having a coil interface surface near the distal end;

wherein the elongate body radially restrains the primary coil in a straight configuration, and the coil may be released by axially restraining the coil against the coil interface surface while proximally withdrawing the elongate body.

25. An intrafallopian contraceptive delivery system as claimed in claim 24, wherein the shaft, the coil interface surface, and the coil are electrically conductive.

26. An intrafallopian contraceptive method comprising:

restraining a resilient structure in a straight configuration, the resilient structure comprising copper and having an isthmus-traversing region which includes at least one bend;

transcervically inserting the restrained resilient structure into an isthmus of a fallopian tube;

releasing the resilient structure within the isthmus, so that the isthmus-traversing region exerts an anchoring force against a wall of the fallopian tube.

27. A method as claimed in claim 26, further comprising:

releasing a distal portion of the resilient structure distally of the target region, the distal portion including at least one bend; and

releasing a proximal portion of the resilient structure proximally of the target region, the proximal portion including at least one bend.

28. A method as claimed in claim 26, wherein the restraining step comprises inserting the resilient structure within a lumen of a catheter, the resilient structure being released within the fallopian tube by axially restraining the resilient structure and proximally withdrawing the catheter.

29. A method as claimed in claim 26, further comprising inhibiting fertilization by exposing a multiplicity of copper fibers within the fallopian tube, the fibers being disposed on the resilient structure.

30. A method as claimed in claim 26, wherein the introducing step comprises:

positioning a distal end of a tubular body adjacent to an ostium;

inserting a delivery catheter containing the resilient structure through the tubular body to the target region, the delivery catheter restraining the resilient body in the straight configuration.

31. A method as claimed in claim 26, further comprising applying an electrical current through the resilient body to the fallopian tube to effect permanent sterilization.

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND THEIR DELIVERY

ABSTRACT OF THE DISCLOSURE

The invention provides intrafallopian devices and non-surgical methods for their placement to prevent conception. The efficacy of the device is enhanced by forming the structure at least in part from copper or a copper alloy. The device is anchored within the fallopian tube by imposing a secondary shape on a resilient structure, the secondary shape having a larger cross-section than the fallopian tube. The resilient structure is restrained in a straight configuration and transcervically inserted within the fallopian tube, where it is released. The resilient structure is then restrained by the walls of the fallopian tube, imposing anchoring forces as it tries to resume the secondary shape.

FIG-1

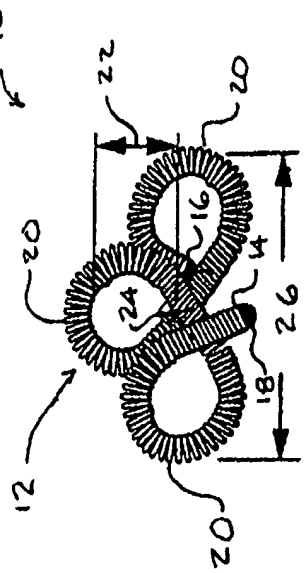


FIG-2

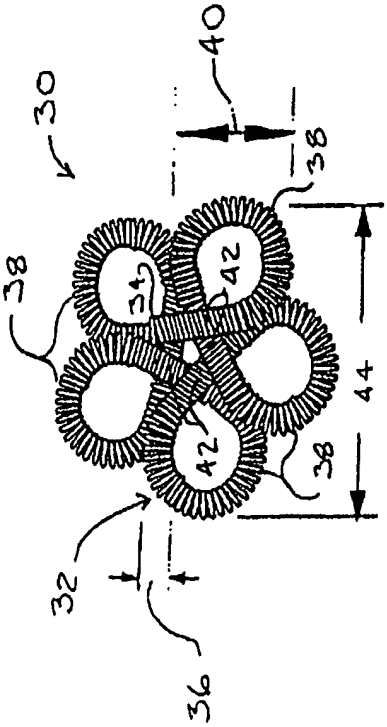
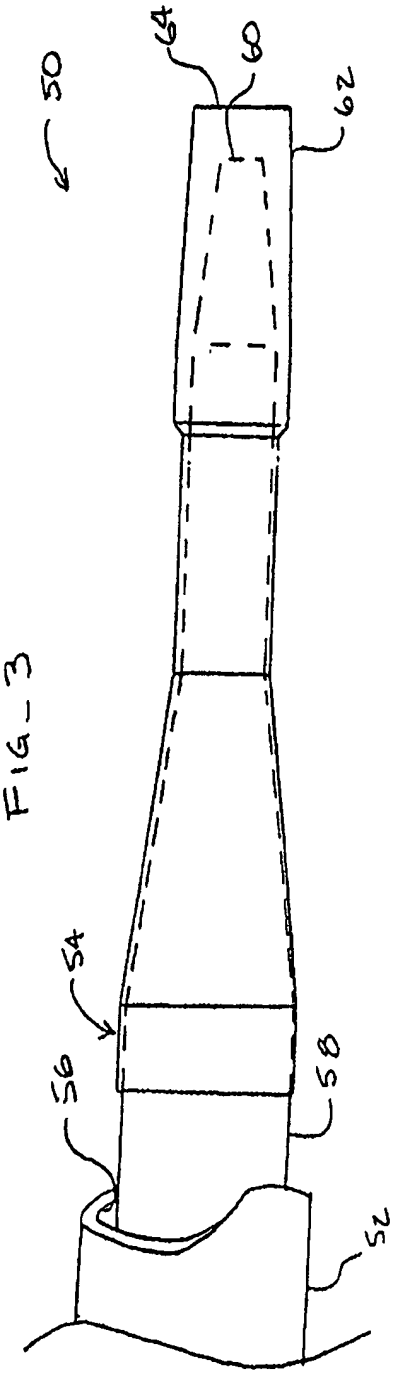


FIG-3



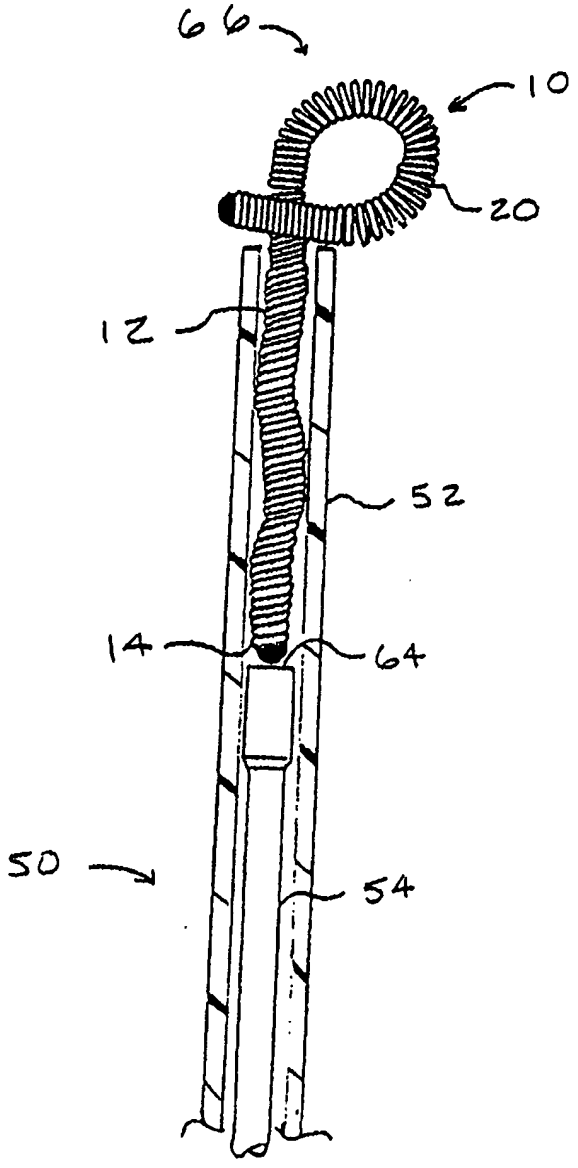


FIG_4

FIG. 5

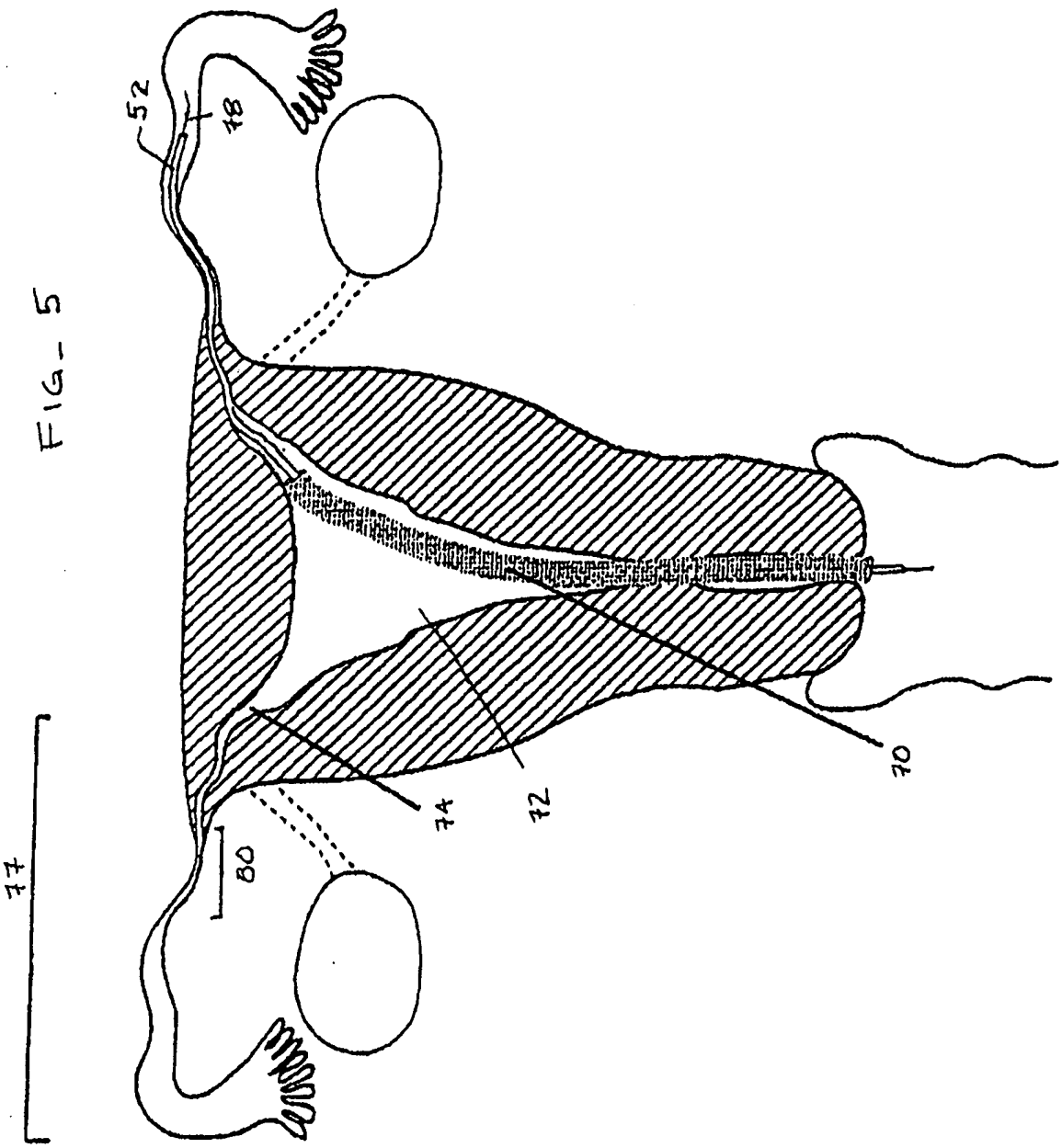


FIG-6

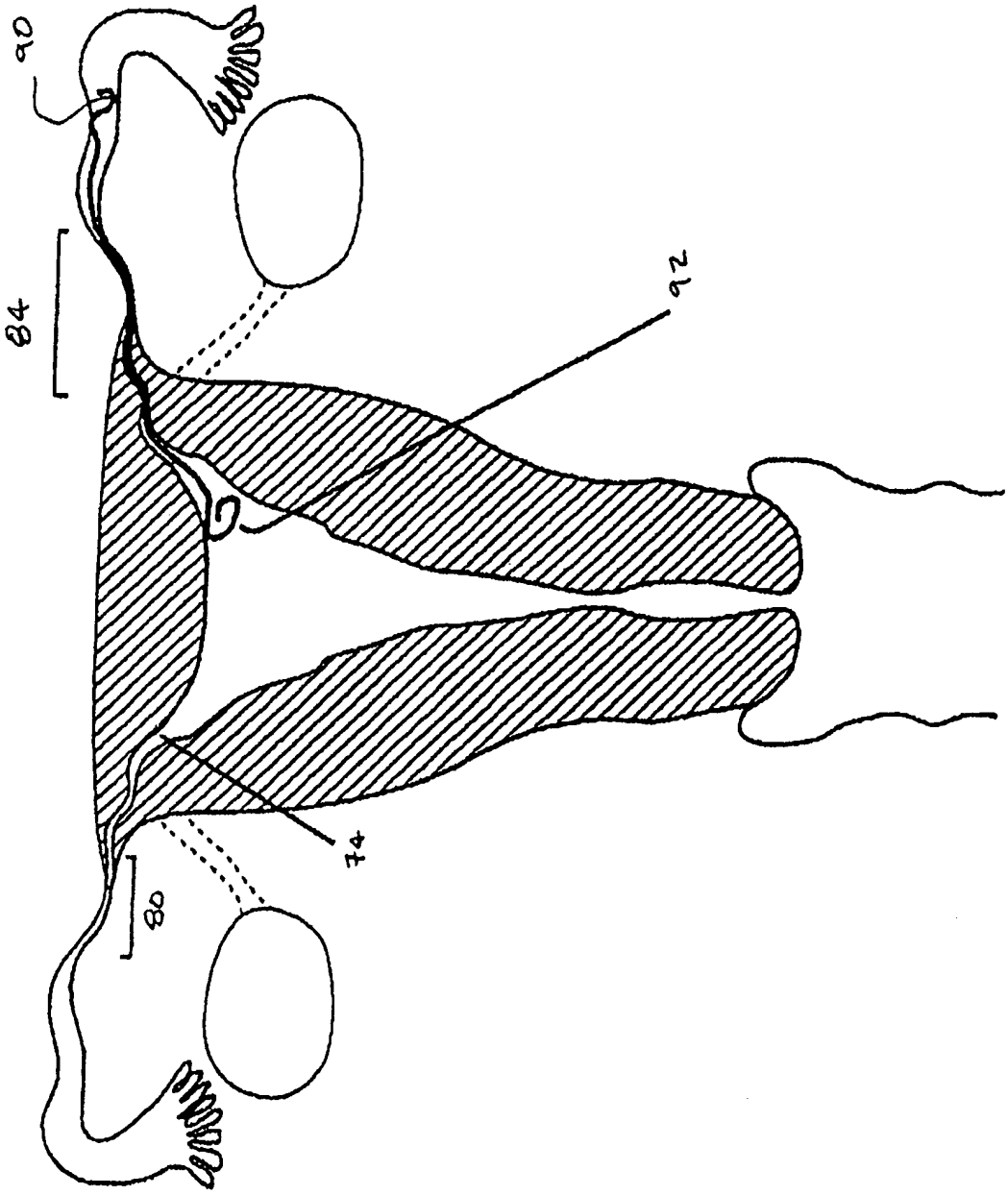


EXHIBIT B

Attorney Docket No. 16355-25
Client Reference No. 95003-1

PATENT APPLICATION

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES HAVING MECHANICAL FALLOPIAN TUBE ATTACHMENT

Inventors:

Julian Nikolchev, a citizen of
The United States, residing at
251 Durazno Way,
Portola Valley, California, 94028;

Dai Ton, a citizen of
The United States, residing at
1693 Flickinger Avenue
San Jose, California, 95131; and

Assignee:

CONCEPTUS, INC.
1021 Howard Avenue
San Carlos, California 94070,
a California corporation.

Status:

SMALL ENTITY

TOWNSEND and TOWNSEND KHOURIE and CREW
Steuart Street Tower, 20th Floor
One Market Plaza
San Francisco, California 94105
(415) 326-2400

(5)

08/475252 A

PATENT
Attorney Docket No. 16355-25

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES HAVING MECHANICAL FALLOPIAN TUBE ATTACHMENT

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to contraception, and more particularly to intrafallopian contraceptive devices and nonsurgical methods for their delivery.

Worldwide demand exists for safe, effective methods of both contraception and permanent sterilization. Although a variety of contraception and sterilization methods are available, all of the existing methods have limitations and disadvantages. Thus, the need for additional safe, low cost, reliable methods of contraception and permanent sterilization, both in developed and less developed countries, is widely recognized.

Many presently available contraception methods require significant user involvement, and user non-compliance results in quite high rates of failure. While the theoretical effectiveness of existing contraceptives, including barrier methods and hormonal therapies, is well established, overcoming user noncompliance to improve overall efficacy has proven difficult.

One form of contraception which is less susceptible to user noncompliance is the intrauterine device (IUD). IUDs have been found to have higher rates of reliability, and are effective for a longer period of time, than most other commercially available contraceptives. Unfortunately, IUDs are also associated with serious infectious complications. For this reason, the use of IUDs within the United States has decreased dramatically. Additionally, IUDs are subject to unplanned expulsion, and must be removed due to excessive pain or bleeding in a percentage of cases, further reducing the

acceptance of the IUD as a contraceptive method. Interestingly, the efficacy of copper IUDs appears to be higher than that of non-metallic IUDs. The reason for this has not been fully explained.

Commercially available options for permanent sterilization include fallopian tube ligation and vasectomy. These methods are surgical, are difficult to reverse, and are not available to many people in the world. It is common knowledge that fertilization occurs in the fallopian tubes where the sperm and ovum meet. Tubal ligation avoids this by complete occlusion of the fallopian tubes.

It has previously been proposed to reversibly occlude the fallopian tubes, for example, by *in vitro* formation of an elastomeric plug, or otherwise anchoring a device on either side of the narrowest region of fallopian tube, called the "isthmus." Such fallopian tube occlusion methods appear promising; however, an unacceptably high percentage of the non-surgical devices proposed to date have become dislodged during previous studies. Even where non-surgical intrafallopian devices have remained in place, they have been found to be only moderately effective at preventing conception.

For these reasons, it would be desirable to provide effective, reliable intrafallopian devices for contraception and sterilization. It would be particularly desirable to provide highly effective intrafallopian devices which did not require surgery for placement. It would be especially desirable if such devices and methods allowed easy placement of the device, but were less susceptible to being dislodged than previously proposed non-surgical intrafallopian devices.

2. Description of the Related Art

The experimental use of a stainless steel intrafallopian device is described in *Transcatheter Tubal Sterilization in Rabbits*, Penny L. Ross, RT 29 "Investigative Radiology", pp. 570-573 (1994). The experimental use of an electrolytically pure copper wire as a surgical contraceptive intrafallopian device in rats was described in "Antifertility

Effect of an Intrafallopian Tubal Copper Device", D.N. Gupta, 14 *Indian Journal of Experimental Biology*, pp. 316-319 (May 1976).

U.K. Patent Application Pub. No. 2,211,095 describes a uterine screw plug for blocking the fallopian tube. European Patent Application Pub. No. 0,010,812 describes a device for placement in the oviducts having enlargements at either end for anchoring the device. The same device appears to be described in Netherlands Patent No. 7,810,696.

The use of tubal occlusion devices is described in "Hysteroscopic Oviduct Blocking With Formed-in-Place Silicone Rubber Plugs", Robert A. Erb, Ph.D., et al., *The Journal of Reproductive Medicine*, pp. 65-68 (August 1979). A formed-in-place elastomeric tubal occlusion device is described in U.S. Patent No. 3,805,767, issued to Erb. U.S. Patent No. 5,065,751, issued to Wolf, describes a method and apparatus for reversibly occluding a biological tube. U.S. Patent No. 4,612,924, issued to Cimber, describes an intrauterine contraceptive device which seals the mouths of the fallopian tubes.

German Patent No. 28 03 685, issued to Brundin, describes a device for plugging a body duct with a device which swells when in contact with a body fluid.

Alternative contraceptive devices are disclosed in copending U.S. Patent Application Serial No. 08/474,779 ~~(attorney docket no. 16355-24)~~, the full disclosure of which is herein incorporated by reference.

SUMMARY OF THE INVENTION

The present invention provides intrafallopian devices and methods for their placement to prevent conception. The intrafallopian devices of the present invention are transcevically delivered and mechanically anchored within the fallopian tube to provide long term contraception, or alternatively permanent sterilization, without the need for surgical procedures or the risks of increased bleeding, pain, and infection associated with intrauterine devices (IUDs).

The intrafallopian devices of the present invention generally comprise a structure having a lumen-traversing region with a helical outer surface. The helical surface is mechanically anchored by a resilient portion of the structure which is biased to form an enlarged secondary shape, preferably forming distal and proximal anchoring loops. The anchoring loops help prevent the helical outer surface from rotating out of position, and also directly deter axial motion within the fallopian tube.

The use of copper in the intrafallopian device of the present invention improves its efficacy as a contraceptive method. Devices formed from plastically deformable materials, however, are less readily restrained in the fallopian tube. Apparently, the large variation in the actual shape and dimensions of fallopian tubes does not provide reliable anchoring for a pre-formed deformable intrafallopian device. The intrafallopian device of the present invention therefore comprises a resilient structure, usually a metallic coil, which includes a copper alloy or plating, ideally comprising an alloy including at least 75% copper. The coil material typically includes beryllium, zinc, stainless steel, platinum, a shape memory alloy, such as Nitinol™, or the like. Preferably, the coil is composed of an alloy of beryllium and copper. Although the present device will generally result in occlusion, it need not completely occlude the fallopian tube to prevent the meeting of the sperm and ovum. Instead, the presence of the copper on the resilient structure is sufficient to provide effective contraception.

Conveniently, the present invention further comprises non-surgical placement of such intrafallopian devices by transcervical introduction. The resilient structure is restrainable in a straight configuration, e.g., by use of a corewire, greatly facilitating and reducing the risks of introduction. Thus, the cost and dangers associated with existing surgical contraceptive and sterilization procedures are avoided.

In a first aspect, a contraceptive intrafallopian device according to the present invention comprises a proximal anchor, a distal anchor, and a lumen-traversing region extending between the anchors. The lumen traversing region has a helical outer surface and a cross-section which is smaller than the cross-sections of the proximal and distal anchors.

Preferably, the lumen-traversing region comprises a resilient structure, generally having a ribbon wound over the outer surface to form the helical shape. Anchoring is enhanced by a sharp outer edge on the ribbon. As described above, at least one of the proximal anchor, the distal anchor, and the lumen-traversing region preferably comprises copper. The proximal and distal anchors generally comprise a resilient structure biased to form an enlarged secondary shape, thereby allowing the device to be restrained in a straight configuration to facilitate transcervical introduction.

In another aspect, a contraceptive intrafallopian device according to the present invention comprises a primary coil having a proximal loop, a distal loop, and an intermediate straight section between the loops. A helical ribbon is wound over at least a portion of the intermediate section, forming a helical surface to mechanically anchor the device within the fallopian tube.

The ribbon of the present intrafallopian device generally protrudes sufficiently to firmly engage the tubal wall. Preferably, the ribbon has a width in the range between .005 and .1 inch, a thickness in the range between .001 and .2 inch, and a pitch in the range between .01 and .2 inch. The overall device geometry preferably facilitates introduction and retention, but is not large or rigid enough to interfere with internal tissue movements. Usually, the device has a length in the range between 1.5 cm and 7.5 cm when in a relaxed state, while the distal loop and the proximal loop have outer diameters of at least 3 mm. Preferably, the primary coil has an outer diameter in the range between .2 mm and 5 mm.

In another aspect, a system for delivering intrafallopian contraceptive devices according to the present invention comprises a primary coil having a proximal loop, a distal loop, and an intermediate straight section between the loops. Additionally, a lumen extends from a proximal end of the proximal loop to near a distal end of the distal loop. A helical ribbon is wound over at least a portion of the intermediate section, forming a helical surface to mechanically anchor the device within the fallopian tube. A corewire is removably disposed within the lumen of the primary coil. The corewire restrains the primary coil in a straight configuration, facilitating trancervical introduction. Optionally, the corewire is threadably received by the primary coil. Alternatively, a release catheter is slidably disposed over the corewire proximally of the primary coil to restrain the primary coil while the corewire is withdrawn proximally from the fallopian tube.

The helical ribbon is anchored in the fallopian tube by the distal and proximal loops. The ribbon is set in the tubal wall while the device is restrained in a straight configuration over a corewire by torquing on the corewire. Withdrawing of the corewire then releases the anchors. The distal anchor is generally inserted into the ampulla, distal of the isthmus, while the proximal anchor is located in the ostium. These anchors prevent rotation of the device, and also help avoid axial movement.

In yet another aspect, an intrafallopian contraceptive method according to the principles of the present invention comprises restraining a resilient contraceptive structure in a straight configuration over a corewire, where the resilient structure includes a lumen-traversing region having a helical outer surface. The resilient structure is transcervically introduced into a target region of a fallopian tube, typically in the region of the ostium, and the corewire is withdrawn from the resilient structure. The resilient structure is mechanically anchored within the fallopian tube, a portion of the resilient structure assuming an enlarged secondary shape which is larger

in cross-section than the fallopian tube. Optionally, an electric current is applied through the resilient structure to the fallopian tube, thereby effecting permanent sterilization.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a first embodiment of a contraceptive intrafallopian device according to the present invention.

Fig. 2 illustrates a primary coil used in the contraceptive intrafallopian device of Fig. 1.

Fig. 3 illustrates a secondary coil which has been imposed on a primary coil as used in the contraceptive intrafallopian device of Fig. 1.

Fig. 4 illustrates a corewire for use with the contraceptive intrafallopian device of Fig. 1.

Fig. 5 is a cross-sectional view of a contraceptive delivery system having the contraceptive intrafallopian device of Fig. 1.

Fig. 6 illustrates an alternative embodiment of the present contraceptive intrafallopian device.

Fig. 7 illustrates a primary coil used in the contraceptive intrafallopian device of Fig. 6.

Fig. 8 schematically illustrates a contraceptive delivery system including the contraceptive intrafallopian device of Fig. 6.

Figs. 9 and 10 illustrates a method of delivery of a contraceptive intrafallopian device according to the present invention.

DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENT

The present invention encompasses a contraceptive intrafallopian device which can alternatively be used as both a permanent and a reversible means of contraception. The present contraceptive methods and devices minimize the danger of non-use which has limited the efficacy of prior art contraceptive techniques. Moreover, the location of the present devices within the fallopian tubes provides a reduced risk of the infectious complications, increased bleeding, and

pelvic pain associated with intrauterine devices (IUDs). The location and the novel shape of the present intrafallopian device provides significant advantages over IUDs, which have been found to be susceptible to unplanned expulsion and removal due to excessive pain and bleeding. The present invention takes advantage of the increase in effectiveness associated with copper IUDs, providing a resilient structure including copper which may be transcervically positioned without the need for surgery.

Although the present contraceptive method is included within a group of contraceptive techniques generally referred to as fallopian tube occlusion methods, the present invention does not necessarily rely solely on blocking the fallopian tube to prevent fertilization. Instead, contraception is apparently provided by disrupting of ovum transport, the process of fertilization, and/or cleavage of the ovum. While the effect that copper has on these processes is not fully understood, it does appear that copper intrafallopian devices offer potentially significant increases in effectiveness over intrafallopian devices formed of other materials. Optionally, the present invention further encompasses devices which promote the growth of tissue within the tube to induce tubal occlusion, further inhibiting conception.

INS. A1

Conveniently, the present resilient structures are adapted to be releasably affixed over a corewire, the corewire restraining the resilient structure in a straight configuration. As the resilient structure has an outer diameter when in the straight configuration which is less than the inner diameter of the fallopian tube, the catheter containing the present intrafallopian device is easily transcervically introduced.

The present invention is anchored within the isthmus of the fallopian tube, overcoming the unintended expulsion of the device and the resulting failure of the contraceptive method. Such intrafallopian device expulsion has been the single greatest factor limiting the efficacy of easily positioned intrafallopian contraceptive techniques. The

present intrafallopian devices are generally elongate resilient structures pre-formed into secondary shapes. These secondary shapes will preferably form anchors proximally and distally of the narrowest portion of the fallopian tube, called the isthmus. The secondary shape must have a larger outer diameter than the inner diameter of the isthmus.

The present device is generally readily removed by snaring the resilient structure near the proximal end and pulling proximally on the resilient structure, thereby straightening the resilient structure and allowing it to be withdrawn without injuring the fallopian tube. Alternatively, an electrical current is applied to the device after it is positioned within the fallopian tube, providing permanent sterilization.

Referring now to Fig. 1, a first embodiment of the present contraceptive intrafallopian device 10 is formed from a resilient primary coil 12. Primary coil 12 has a proximal end 14 and a distal end 16, the latter having an atraumatic endcap 18. Primary coil 12 further includes three portions: a proximal anchor portion 20, a distal anchor portion 22, and a lumen-traversing region 24. Proximal and distal anchors 20,22 are biased to form anchoring loops 26, as described hereinbelow.

Lumen-traversing region 24 comprises a substantially straight portion of primary coil 12. A ribbon 28 is wound over the outer surface of primary coil 12 to provide a helical shape. Ribbon 28 includes sharp outer edges 29, which firmly anchor lumen-traversing region 24 in the fallopian tube wall when torque is applied to intrafallopian device 10. The ribbon is preferably formed of a high strength biocompatible metal, ideally being stainless steel. The ribbon is attached to primary coil 12 at a proximal joint 30 and a distal joint 32, which may be formed of solder, heat-shrink tubing, or the like.

Referring now to Fig. 2, primary coil 12 is most easily formed in a straight configuration as a cylindrical coil or spring, preferably having an outer diameter in the range from .005 inch to .05 inch, and having a length in the

range from 20 mm to 150 mm. Ideally, primary coil 12 has an outer diameter in the range from .01 inch to .05 inch and a length in the range from 30 mm to 125 mm.

Preferably, primary coil 12 is formed from a beryllium copper alloy wire. Beryllium copper provides the resilience necessary to avoid expulsion of the device, and also provides the increased effectiveness of a copper contraceptive intrafallopian device. Such a beryllium copper wire will typically have a diameter from .002 inch to .01 inch. To provide the increased efficacy of a copper intrafallopian device, primary coil 12 preferably comprises an alloy including 75% copper. Alternatively, primary coil 12 is formed from a resilient metal, such as stainless steel, platinum, a shape memory alloy, or the like. If such materials are used, primary coil 12 is preferably plated with copper or a copper alloy or otherwise has copper attached.

Primary coil 12 includes a body winding 42 and a thread winding 44. Body winding 42 is formed with the minimum possible pitch to increase the stiffness of primary coil 12. Thread winding 44 will typically comprise from 0.1 cm to 2 cm adjacent to proximal end 14, and will have a pitch roughly twice that of body winding 42.

Referring now to Fig. 3, the proximal and distal anchors are formed by imposing a bent secondary shape on selected portions of primary coil 12. The secondary shape preferably comprises loops 26 formed by bending primary coil 12, and heat treating the primary coil while it is bent. A wide variety of secondary shapes may be used, including sinusoidal curves, alternating loops, or loops separated by straight sections so as to form a "flower coil," as more fully described in copending U.S. Patent Application Serial No. 08/424,778 ~~(Attorney Docket No. 16355-24)~~ the full disclosure of which is herein incorporated by reference. In all cases, the bent secondary shape should have an outer cross-section 46 which is larger than the fallopian tube to provide effective anchoring.

Referring now to Fig. 4, a corewire 50 for use with intrafallopian device 10 (Fig. 1) comprises a resilient wire

52 which tapers towards a distal end 54. Wire 52 is sufficiently stiff to restrain intrafallopian device 10 in a straight configuration, typically comprising stainless steel, platinum, or the like. A short section of coil forms corewire threads 56 attached at threadjoint 58. Threads 56 match the windings and pitch of threadwindings 44 of primary coil 12.

Referring now to Fig. 5, an intrafallopian contraceptive system 60 comprises corewire 50 inserted within a lumen 62 through intrafallopian device 10. Intrafallopian device 10 is releasably attached by engaging thread windings 44 with threads 56. Thus, intrafallopian device 10 is disengaged by torquing a proximal end of corewire 50 once intrafallopian device 10 is in position.

Referring now to Fig. 6, an alternative embodiment of the present intrafallopian device is again formed from a resilient primary coil 112 having a proximal end 114 and a distal end 116. The former includes a friction fitting 115. Primary coil 112 again includes three portions: a proximal anchor portion 120, a distal anchor portion 122, and a lumen-traversing region 124. Proximal and distal anchors 120, 122 are here biased to form opposed anchoring loops 26, thereby increasing the relaxed overall cross-section of the proximal and distal anchors. A ribbon 128 is wound over the outer surface of primary coil 112 to provide a helical shape, as described above.

Referring now to Fig. 7, primary coil 112 comprises a uniform body winding 142. The secondary shape is imposed on the straight cylindrical coil as opposed loops 126, or alternatively as multiple loops of a flower coil.

Referring now to Fig. 8, an intrafallopian contraceptive system using alternative intrafallopian device 100 includes a corewire 152 which tapers towards a distal end 154. Friction fitting 115 fittingly engages corewire 152, which restrains primary coil 112 in a straight configuration. A release catheter 164 is slidably disposed over corewire 152 proximally of alternative intrafallopian device 100, allowing the device to be released by withdrawing corewire 152 relative to the release catheter.

Use of the present contraceptive intrafallopian device will be described with reference to Figs. 9 and 10. A uterine introducer canula 70 is inserted transcervically through a uterus 72 to the region of an ostium 74. Alternatively, a hysteroscope may be used in place of canula 70.

Intrafallopian contraceptive system 60 is advanced distally of introducer cannula 70 and manuevered through the fallopian tube, preferably until intrafallopian device 10 extends distally of the isthmus. Optionally, intrafallopian contraceptive system 60 is self-guided, with corewire 52 bent near distal end 54 to assist intraluminal manuevering. Alternatively, a guide wire and catheter are advanced into the fallopian tube first, and the guide wire is replaced with intrafallopian contraceptive system 60. In either case, the intrafallopian device is axially positioned with lumen-traversing region 24 within a target region 84 adjacent to isthmus 80. Preferably, at least one loop of distal anchor 22 is distal of target region 84, and at least one loop of proximal anchor 20 is proximal of target region 84 to form the distal and proximal anchor bends.

Once intrafallopian device 10 is properly positioned, corewire 50 is torqued to set ribbon 28 in the tubal wall. The corewire may then be unthreaded from intrafallopian device 10 by rotating the corewire in the opposite direction, disengaging threads 56 from thread windings 44. The corewire is then free to slide proximally, releasing the primary coil. As the distal end of the primary coil is released, a distal anchor bend 90 is formed. Similarly, a proximal loop forms a proximal anchor bend 92. The anchor bends help to axially restrain the device within the fallopian tube, and also prevent rotation around the helical shape of lumen-traversing region 24. As seen in Fig. 10, the loops need not assume their relaxed form to provide effective distal or proximal anchors.

The present invention further encompasses permanent sterilization by passing a current through the corewire to the intrafallopian device prior to withdrawing the corewire.

Fallopian tube tissue in contact with the intrafallopian device is dessechated, and thus attached to the present intrafallopian device. This action also causes permanent tubal damage, leading to the formation of scar tissue which encapsulates the intrafallopian device and causes permanent occlusion of the tubal lumen. Clearly, the corewire/primary coil interface must be conductive to allow the present non-surgical method of permanent sterilization.

In conclusion, the present invention provides a contraceptive intrafallopian device which may be positioned without surgery. While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. For example, a wide variety of secondary shapes, including open loops, continuous bends, sinusoidal curves, or the like, may be imposed on the primary coil. Therefore, the above description should not be taken as limiting the scope of the invention, which is defined instead solely by the appended claims.

WHAT IS CLAIMED IS:

1. An intrafallopian contraceptive device comprising:

a proximal anchor having a proximal cross-section;

a distal anchor having a distal cross-section; and

a lumen-traversing region extending between the proximal anchor and the distal anchor, the lumen traversing region having a helical outer surface and a helical cross-section which is smaller than both the proximal cross-section and the distal cross-section.

2. An intrafallopian contraceptive device as claimed in claim 1, wherein the lumen-traversing region comprises a resilient structure.

3. An intrafallopian contraceptive device as claimed in claim 2, wherein the lumen-traversing region further comprises a ribbon wound over the outer surface of the resilient structure.

4. An intrafallopian contraceptive device as claimed in claim 2, wherein the ribbon includes a sharp outer edge.

5. An intrafallopian contraceptive device as claimed in claim 1 wherein at least one of the proximal anchor, the distal anchor, and the lumen-traversing region comprises copper.

6. An intrafallopian contraceptive device as claimed in claim 1 wherein at least one of the proximal anchor and the distal anchor comprises a resilient structure biased to form a secondary shape.

7. An intrafallopian contraceptive device as claimed in claim 6, wherein the resilient structure comprises a primary coil.

8. An intrafallopian contraceptive device as claimed in claim 7, wherein the primary coil comprises a material selected from the group consisting of beryllium, stainless steel, platinum, and shape memory alloy.

9. An intrafallopian contraceptive device as claimed in claim 8, wherein the primary coil comprises an alloy including beryllium and copper.

10. An intrafallopian device as claimed in claim 7, wherein the primary coil comprises an alloy including at least 75% copper.

11. An intrafallopian contraceptive device as claimed in claim 1, wherein a lumen extends from a proximal end of the proximal anchor to near a distal end of the distal anchor.

12. An intrafallopian contraceptive device comprising:

a primary coil having a distal loop, a proximal loop, and an intermediate straight section between the distal loop and the proximal loop; and

a helical ribbon wound over at least a portion of the intermediate section.

13. An intrafallopian contraceptive device as claimed in claim 12, wherein the ribbon has a width in the range between .005 and .1 inch.

14. An intrafallopian contraceptive device as claimed in claim 13, wherein the ribbon has a thickness in the range between .001 and .2 inch.

15. An intrafallopian contraceptive device as claimed in claim 12, wherein the ribbon has a pitch in the range between .01 and .2 inch.

16. An intrafallopian contraceptive device as claimed in claim 12, wherein the device has a length in the range between 1.5 cm and 7.5 cm when in a relaxed state.

17. An intrafallopian contraceptive device as claimed in claim 12, wherein the device comprises copper.

18. An intrafallopian contraceptive device as claimed in claim 17, wherein the primary coil comprises a material selected from the group consisting of beryllium, stainless steel, platinum, and shape memory alloy.

19. An intrafallopian contraceptive device as claimed in claim 18, wherein the primary coil comprises an alloy including beryllium and copper.

20. An intrafallopian contraceptive device as claimed in claim 12, wherein the primary coil includes a lumen which extends from a proximal end of the proximal loop to near the distal end of the distal loop.

21. An intrafallopian contraceptive device as claimed in claim 12, wherein the primary coil has an outer diameter in the range between .2 mm and 5 mm.

22. An intrafallopian contraceptive device as claimed in claim 12, wherein the distal loop and the proximal loop have outer diameters of at least 3 mm when in a relaxed state.

23. An intrafallopian contraceptive system comprising:

a primary coil having a distal loop, a proximal loop, an intermediate straight section between the distal loop and the proximal loop, and a lumen from a proximal end of the proximal loop to near a distal end of the distal loop;

a helical ribbon wound over at least a portion of the intermediate section; and

a corewire removably disposed within the lumen of the primary coil, the corewire restraining the primary coil in a straight configuration.

24. An intrafallopian contraceptive system as claimed in claim 23, wherein the primary coil comprises copper.

25. An intrafallopian contraceptive system as claimed in claim 23, wherein the corewire is threadably received by the primary coil.

26. An intrafallopian contraceptive system as claimed in claim 23, further comprising a release catheter slidably disposed over the corewire proximally of the primary coil, the release catheter having a distal primary coil engaging surface for restraining the primary coil while the corewire is withdrawn proximally.

27. An intrafallopian contraceptive method comprising:

restraining a resilient structure in a straight configuration over a corewire, the resilient structure including a lumen-traversing region having a helical outer surface;

transcervically introducing the resilient structure into a target region of a fallopian tube; and

withdrawing the corewire from the resilient structure to mechanically anchor the resilient structure within the fallopian tube, at least a portion of the resilient structure assuming a secondary shape which is larger in cross-section than the fallopian tube.

28. A method as claimed in claim 27, wherein the target region is adjacent to an ostium of the fallopian tube.

29. A method as claimed in claim 28, wherein the target region extends distally of an isthmus of the fallopian tube.

30. A method as claimed in claim 27, further comprising torquing the corewire to anchor the resilient structure, the helical shape having a sharp outer edge.

31. A method as claimed in claim 27, wherein the withdrawing step comprises forming a distal anchor from a portion of the resilient structure which is distal of the lumen-traversing region, and forming a proximal anchor from a portion of the resilient structure which is proximal of the lumen-traversing region, the distal portion and the proximal portion assuming the secondary shape.

32. A method as claimed in claim 27, wherein the withdrawing step comprises unthreading the corewire from the resilient structure.

33. A method as claimed in claim 27, wherein the withdrawing step comprises axially restraining the resilient structure with a release catheter, the release catheter being slidably disposed over the corewire proximally of the resilient structure.

34. A method as claimed in claim 27, further comprising applying an electrical current through the resilient structure to the fallopian tube to permanently prevent conception.

35. An intrafallopian sterilization method comprising:

transcervically introducing a structure into a target region of a fallopian tube, the structure being releasably attached to a distal end of an elongate body;

applying an electrical current through the elongate body to the structure, and through the structure to the fallopian tube to permanently anchor the structure within the fallopian tube; and

releasing the structure from the elongate body and withdrawing the elongate body.

Add 87

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES HAVING MECHANICAL FALLOPIAN TUBE ATTACHMENT

ABSTRACT OF THE DISCLOSURE

The invention provides intrafallopian devices and non-surgical methods for their placement to prevent conception. The efficacy of the device is enhanced by forming the structure at least in part from copper or a copper alloy. The device is anchored within the fallopian tube by a lumen-traversing region of the resilient structure which has a helical outer surface, together with a portion of the resilient structure which is biased to form a bent secondary shape, the secondary shape having a larger cross-section than the fallopian tube. The resilient structure is restrained in a straight configuration and transcervically inserted within the fallopian tube, where it is released. Optionally, permanent sterilization is effected by passing a current through the resilient structure to the tubal walls.

16 15-25
SHT 1 OF 5

08/475252

S-1
330

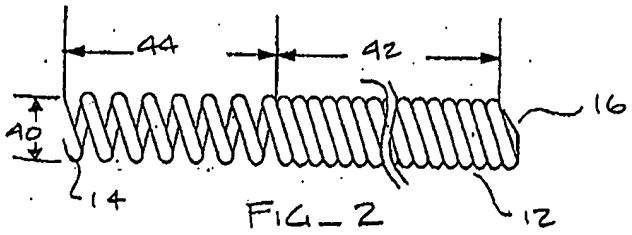


FIG_2

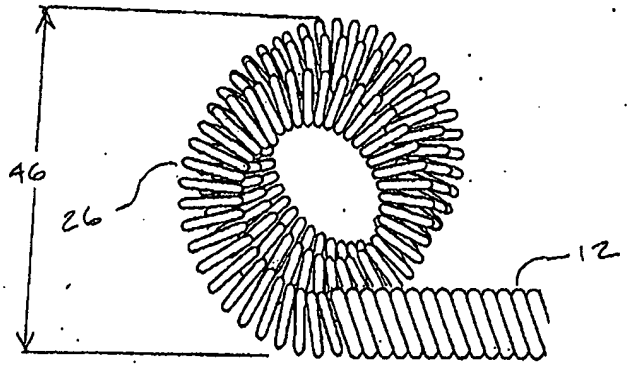


FIG_3

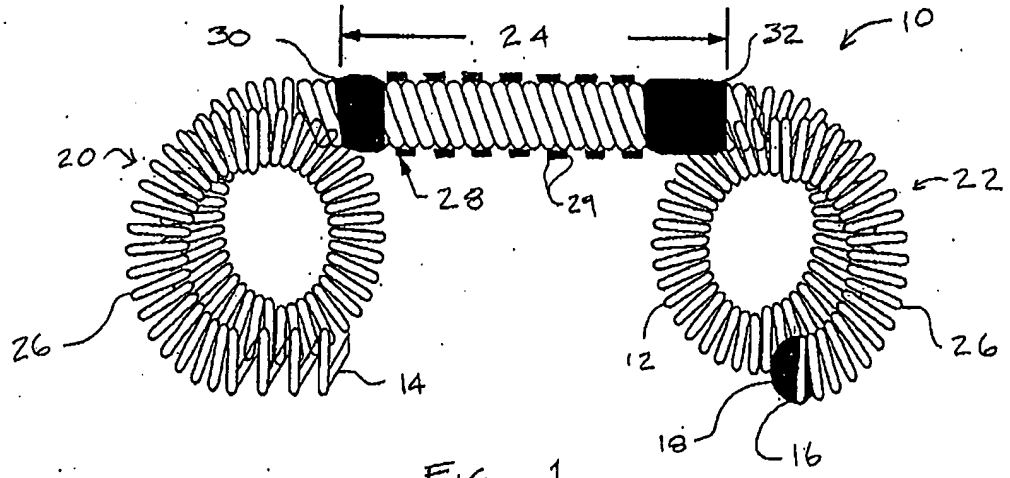


FIG_1

FIG_4

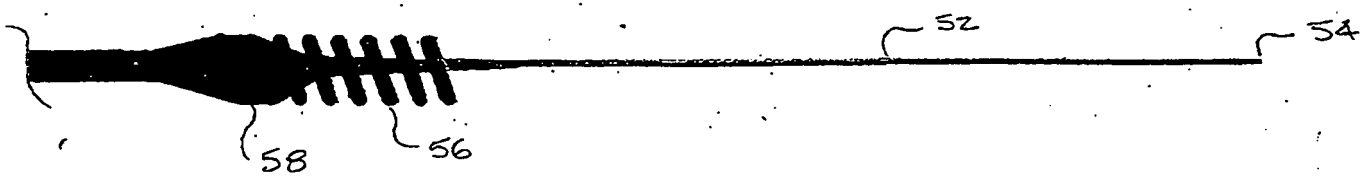


FIG_5

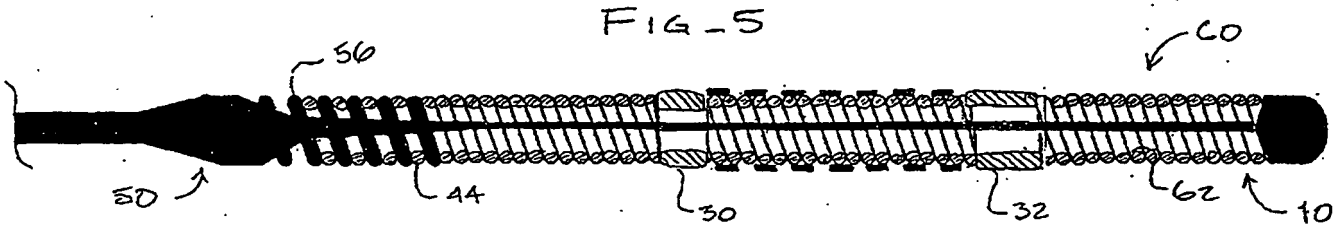


FIG_8

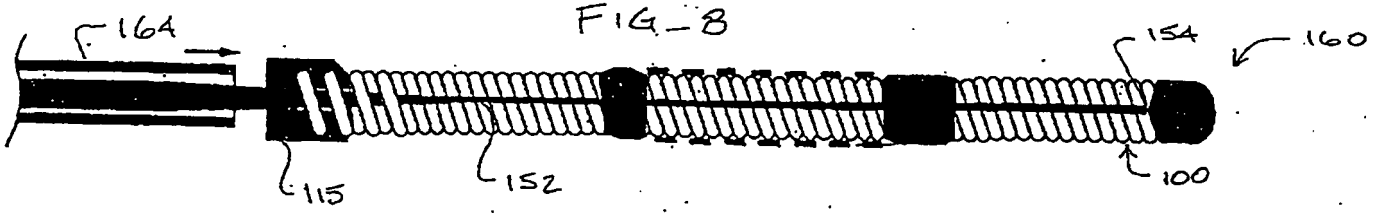
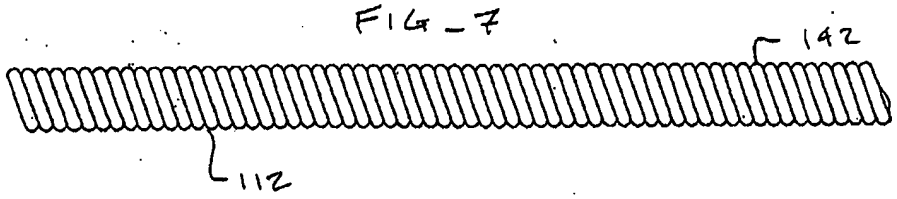


FIG-7



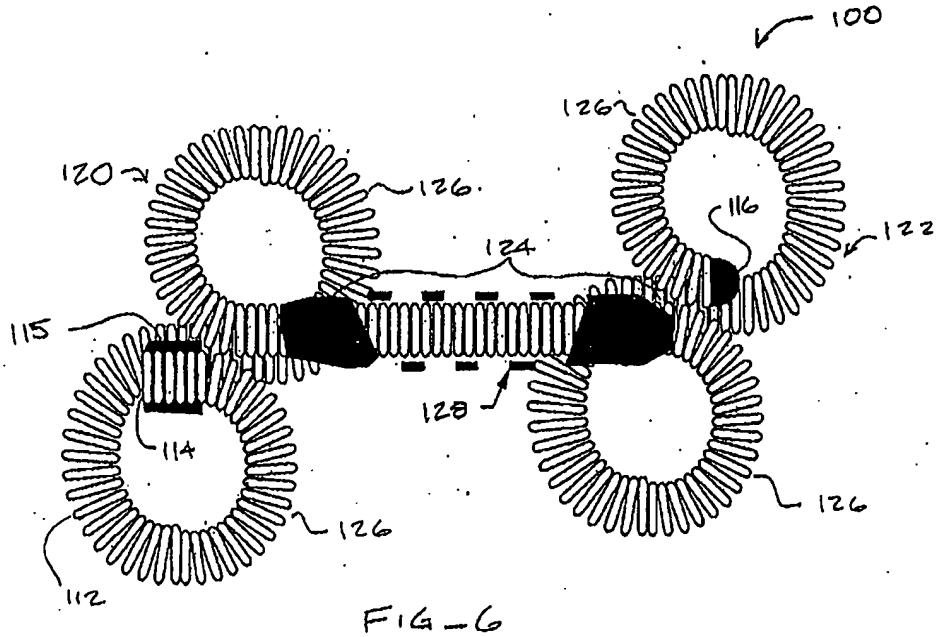


FIG-6

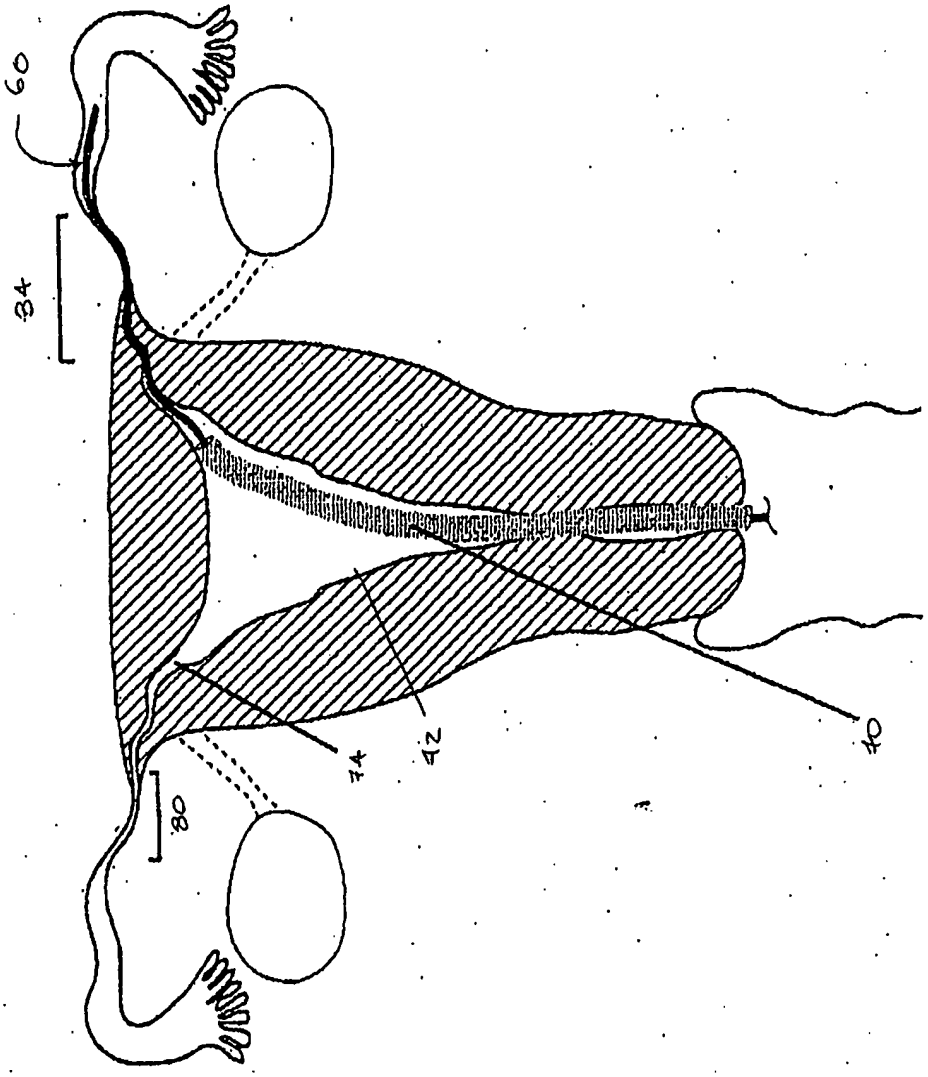


FIG-9

16355-25
SHT 5 OF 5

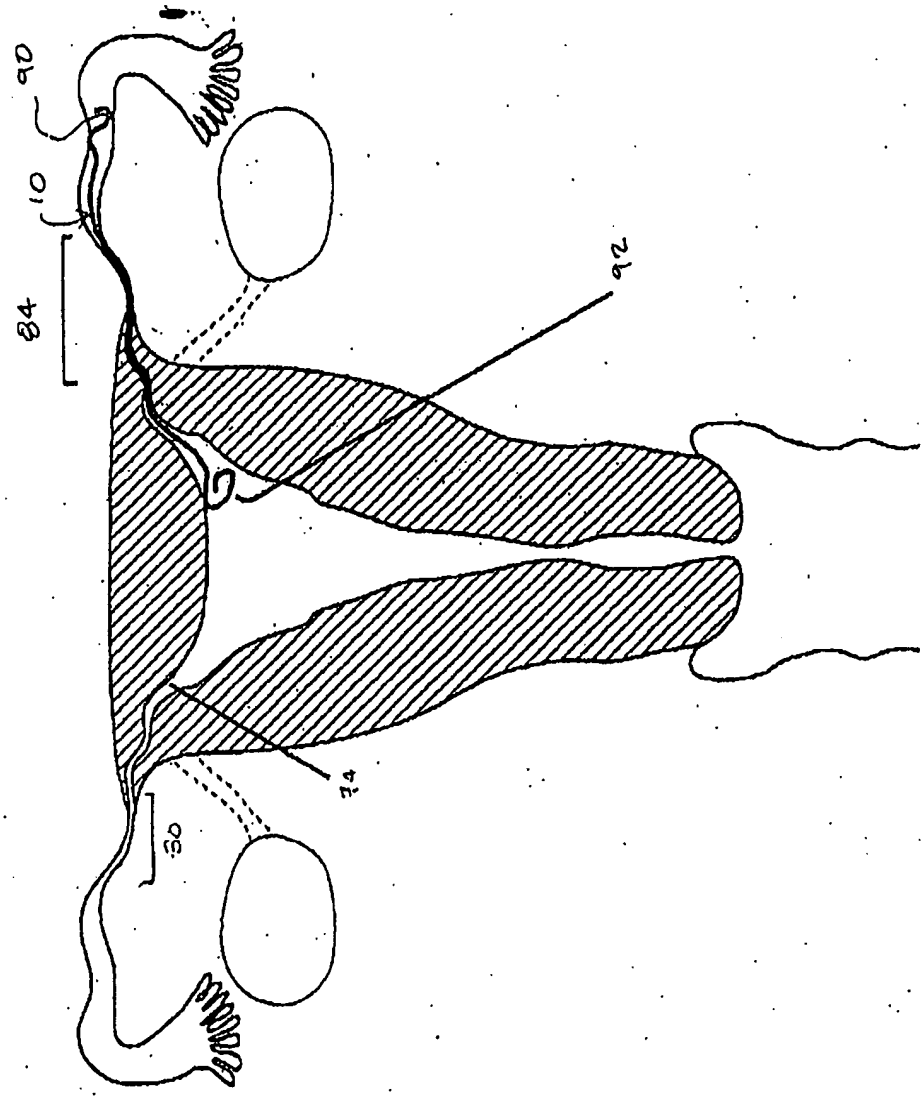


FIG-10

PRINT OF DRAWI[illegible]
AS ORIGINALLY [illegible]

3355 - 25
SHT 1 OF 5

08/475252
5-1
330

128/831

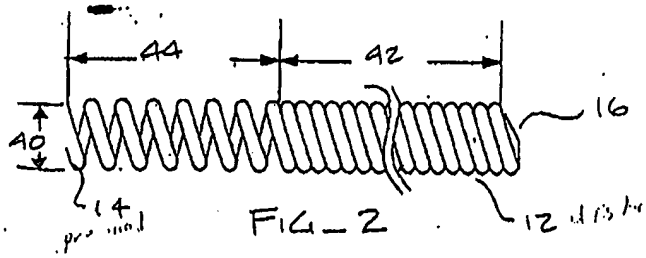


FIG_2

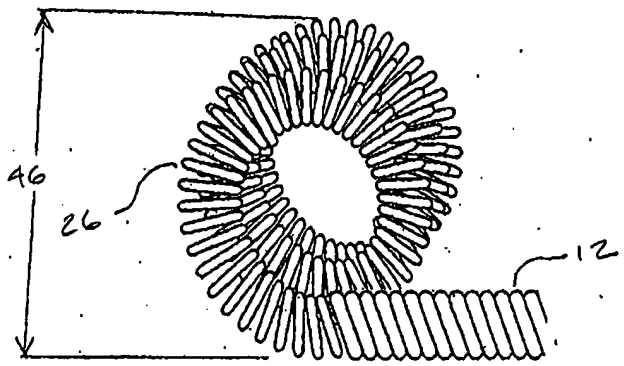


FIG_3

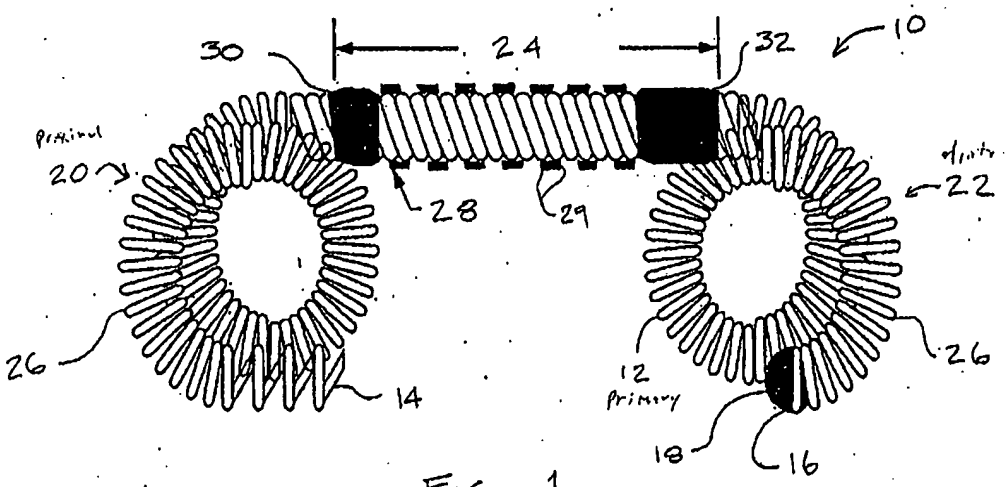


FIG_1

4/32

PRINT OF DRAWINGS AS ORIGINALLY FILED

16355-25
SHT 2 OF 5

08/475252

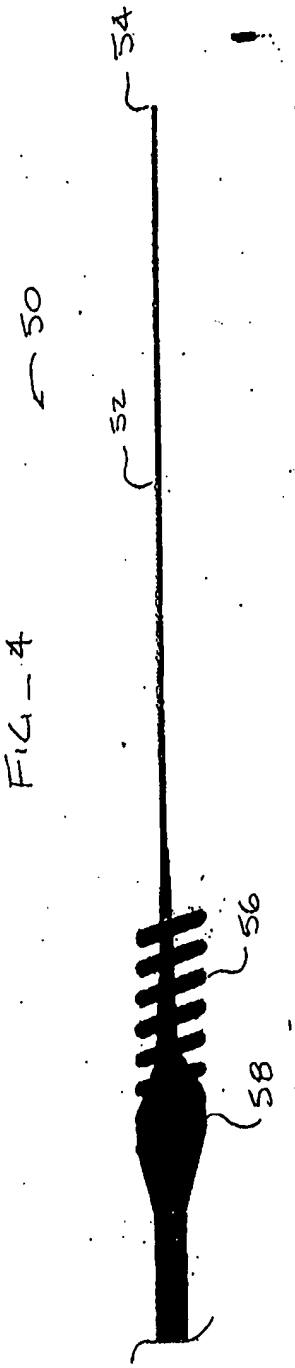


FIG-4

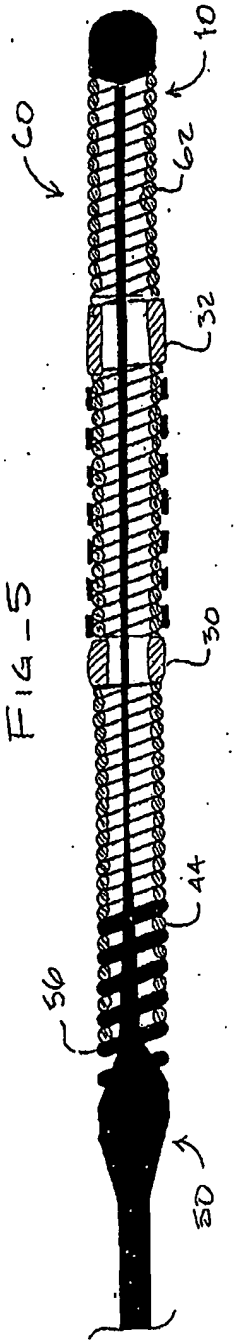


FIG-5

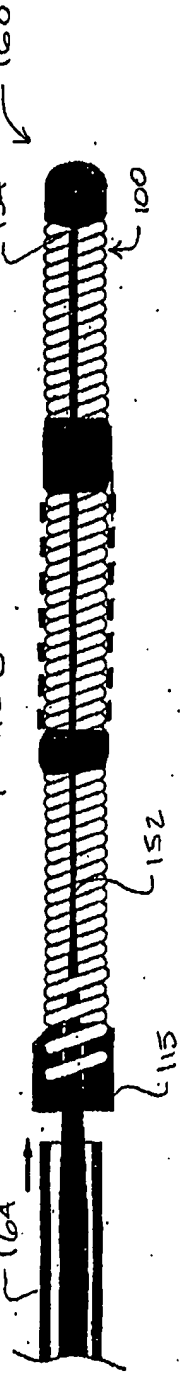
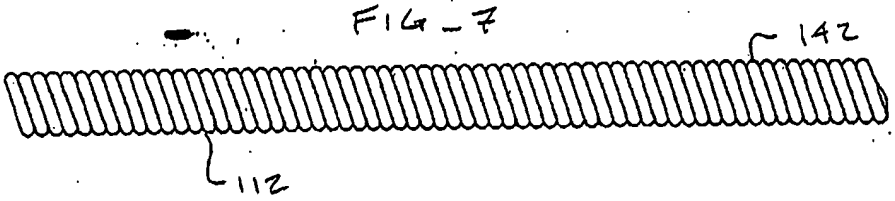


FIG-8

08/475252

FIG-7



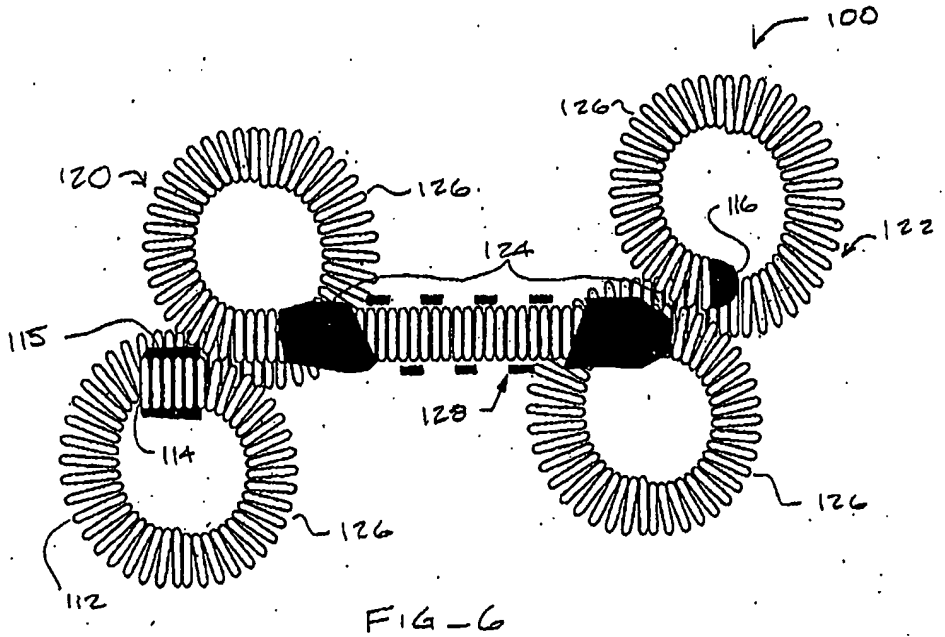


FIG-6

6355-25
SHT 4 OF 5

08/475252

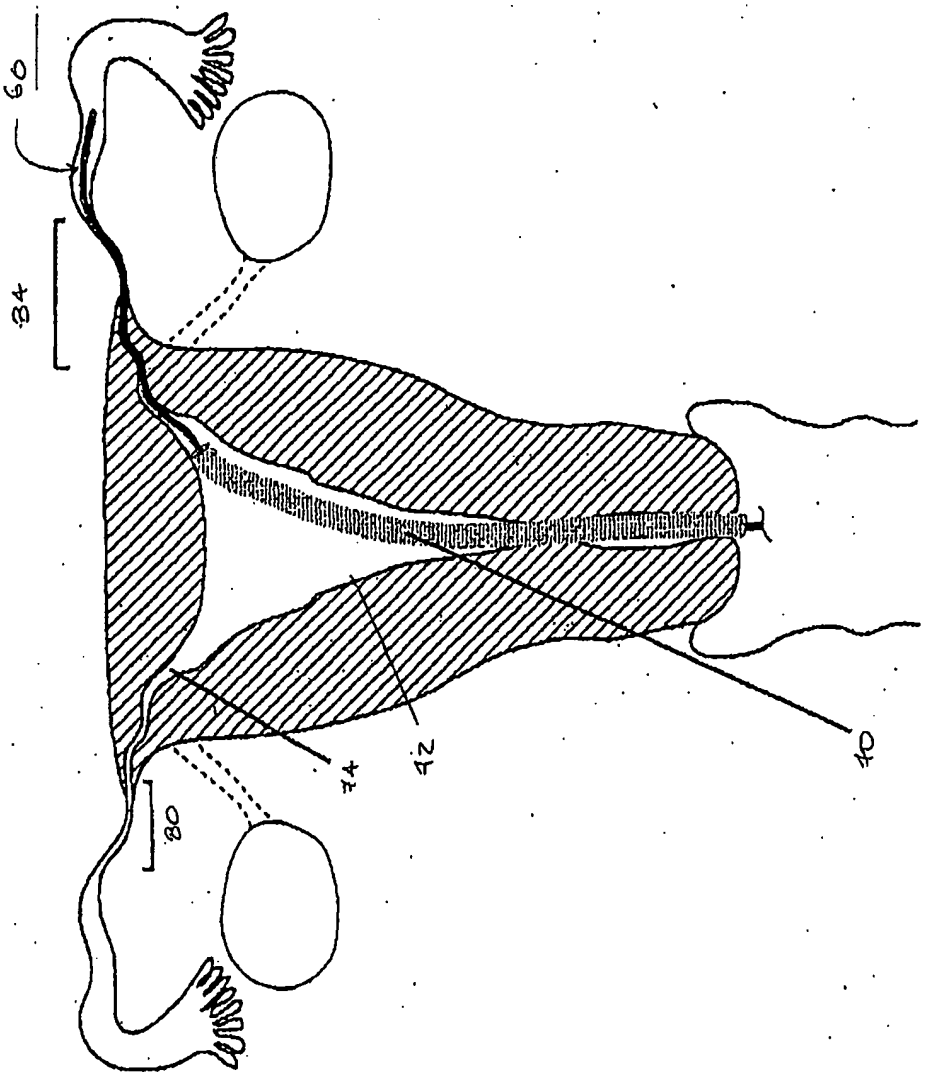


FIG-9

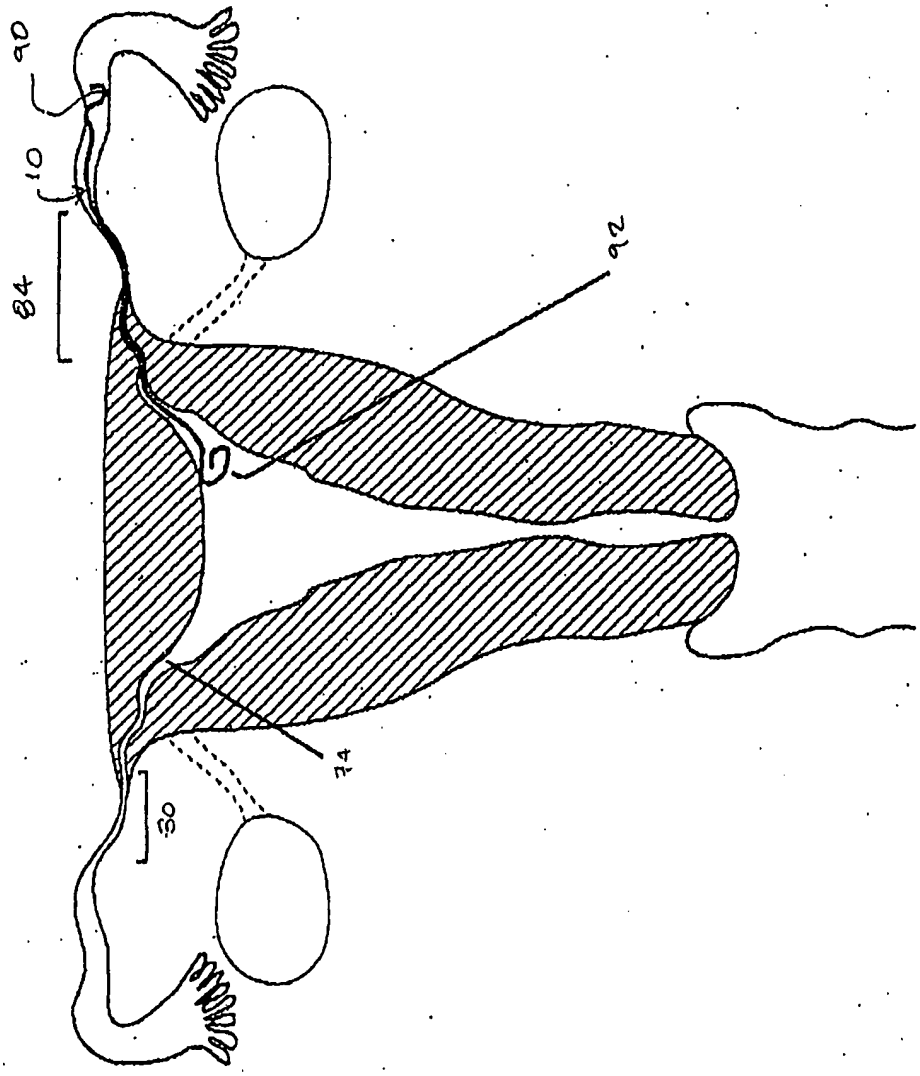


FIG-10

EXHIBIT C

REDACTED

Conceptus

Date: _____

Invention Disclosure

Invention Disclosure #: 95003-1

Names of Inventors: Julian Nikolchev
Dai Ton

INSTRUCTIONS: Please provide the information requested. Please sign this form and have your signature witnessed where noted. Submit this form to the Patent Coordinator.

Short Title of Invention: Intrafallopian Tube Device for Permanent or Reversible Contraception.

I. Purpose

Transcervical Intrafallopian Tube Device with mechanical means for attachment for permanent or reversible contraception.

The Invention:

a) Background (circumstances that led to the invention)

It is common knowledge that fertilization occurs in the fallopian tubes, where sperm and ovum meet. Thus it is believed that the most effective means for contraception would be by placing a device in the fallopian tube which would either prevent the sperm and ovum from ever encountering each other, or would prevent fertilization from occurring once they do meet.

IUD's are some of the most well known and most effective devices for contraception. While their function is not completely understood, it is known that IUD's combining copper are very effective in preventing undesirable pregnancies. IUD's, however, are also limited in their effectiveness due to unplanned expulsion or removal due to excessive pain or bleeding. Placing a device in each fallopian tube, which in addition, can provide the active functionality of pregnancy prevention due to the use of copper materials would be very attractive and a significantly improved method for reversible or permanent contraception.

II. Description

a) Describe invention (including the problem to be solved by the invention and the structure of the invention)

This invention provides for an accurate delivery of an Intrafallopian Tube Device (IFD) in a desired place of a fallopian tube, mechanically anchoring the device in place, and detaching the delivery wire from the device, leaving the IFD in the tube.

This IFD is manufactured in an assembled fashion including a guidewire for delivery. The IFD composes the distal part of the wire. The IFD is attached to the wire by means of an interlocking screwing mechanism, designed to release the IFD if the IFD is held motionless relative to the core wire while the core wire is torqued counter-clockwise.

The assembled core wire and IFD can be delivered into the fallopian tube through a number of standard methods for transcervical fallopian tube access. For example, it can be delivered through the working channel of a hysteroscope, or through the lumen of a uterine cannula designed to be placed at the ostium of a fallopian tube. It is placed in the tube, using normal guidewire techniques.

The design of the IFD is based on a coil, with cylindrical primary shape, designed to be smaller diameter than the fallopian tube lumen, and a secondary shape, designed to be larger diameter than the fallopian tube lumen. The middle of this coil has an added construction composed of a larger coil made from a ribbon material (rather than typical cylindrical wire). This coil, attached to the smaller coil, provides an effective means for anchoring the IFD inside the tube. It's structure being basically a screw, the IFD can be anchored by torquing the device clockwise using the core wire. Since the tubal lumen is a potential space, the sharp corners of the ribbon coil can grab the tissue and become anchored. Once the device has been properly attached, the core wire can be detached by torquing it counter-clockwise, thereby disengaging it from the holding mechanism.

If a stronger or more permanent action is desired, a small current can be applied through the core wire to the IFD, prior to disengaging. This will cause dessechation of the tissue in contact with the IFD, leading to the growth of scar tissue, permanently encapsulating the IFD and occluding the fallopian tube.

Materials:
core wire -- stainless steel (ss)
IFD -- can be ss, platinum, either coated with copper or copper alloy, such as berrillium/copper.

REDACTED

II. Description (continued)
b) Invention Drawing:

Attached.

REDACTED

III. Chronological description of activities undertaken to make the invention. Please indicate who carried out each step and who witnessed each step. (Use separate sheet of paper if necessary.)

1. Device prototyped in Conceptus. by Julian Nikolchev and Dai Ton at

2. Device tested in in-vitro models in and

REDACTED

If the invention is being used in a Conceptus' commercial process or product, give an estimate of first date of such use: _____

Used since:

In:

If the invention has been or will be disclosed outside the company, please recite the circumstances.

On:

If the invention has not been disclosed outside the company, please do not disclose it outside the company without prior agreement of patents coordinator.

REDACTED

INVENTORS:

(signature)

Julian Mihelcheu
(printed, name)

251 Durazno Way
Street Address

Portola Valley CA 94028
City, State, Zip

Citizenship

(signature)

DAI TON
(printed name)

1693 FLICKINGER AVE
Street Address

SAN JOSE CA 95131
City, State, Zip

US Citizen
Citizenship

(signature)

(printed name)

(date)

Street Address

Street Address

City, State, Zip

Citizenship

(signature)

(printed name)

(date)

Street Address

Street Address

City, State, Zip

Citizenship

(signature)

(printed name)

(date)

Street Address

Street Address

City, State, Zip

Citizenship

(signature)

(printed name)

(date)

Street Address

Street Address

City, Sate, Zip

Citizenship

REDACTED

WITNESSES:

(signature)

Charles Dilts
(printed name)

(date)

(signature)

(printed name)

(date)

32407 Montevez Dr
Street Address

Union City CA 94587
Street Address

City, State, Zip

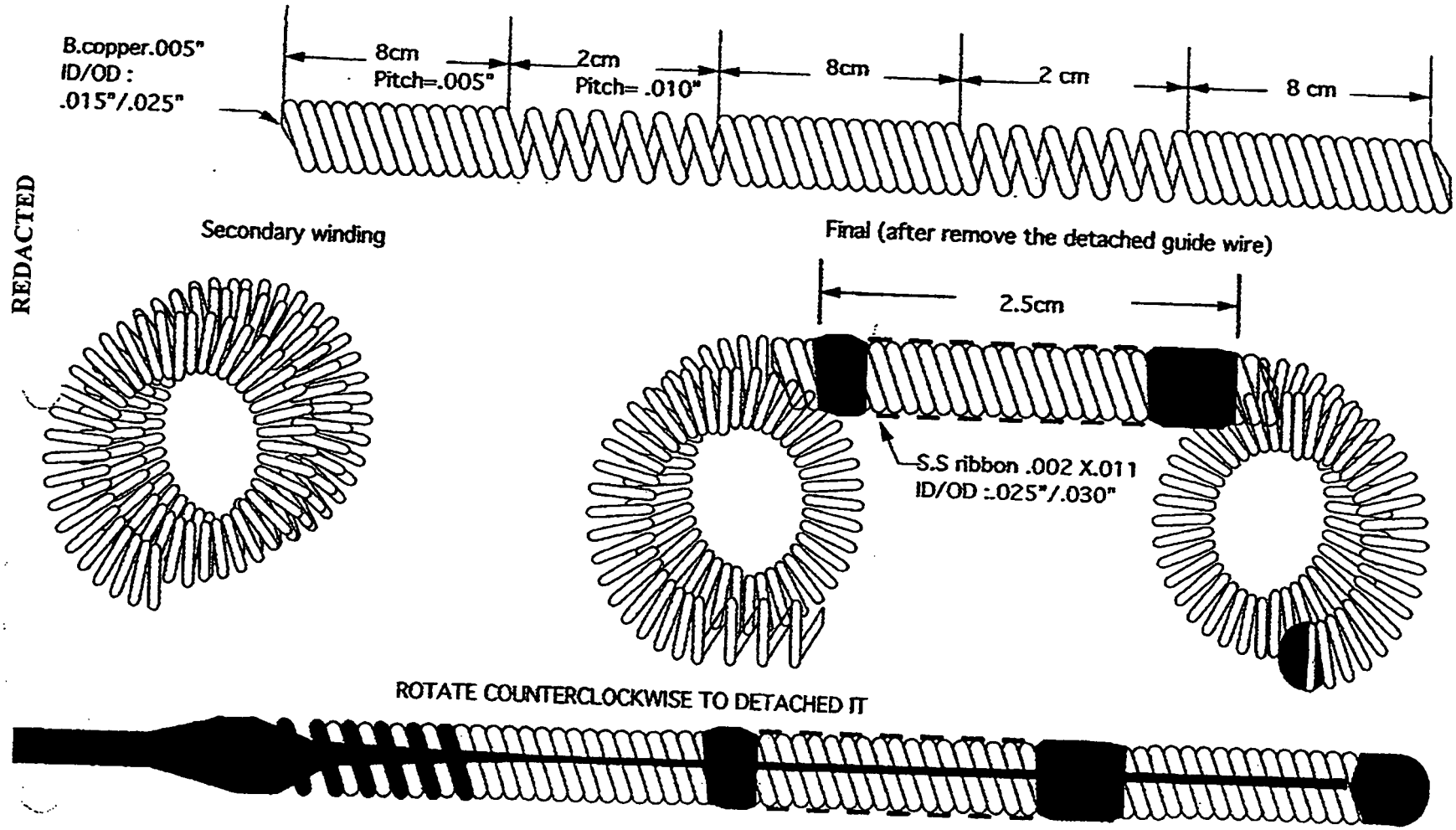
Citizenship

Street Address

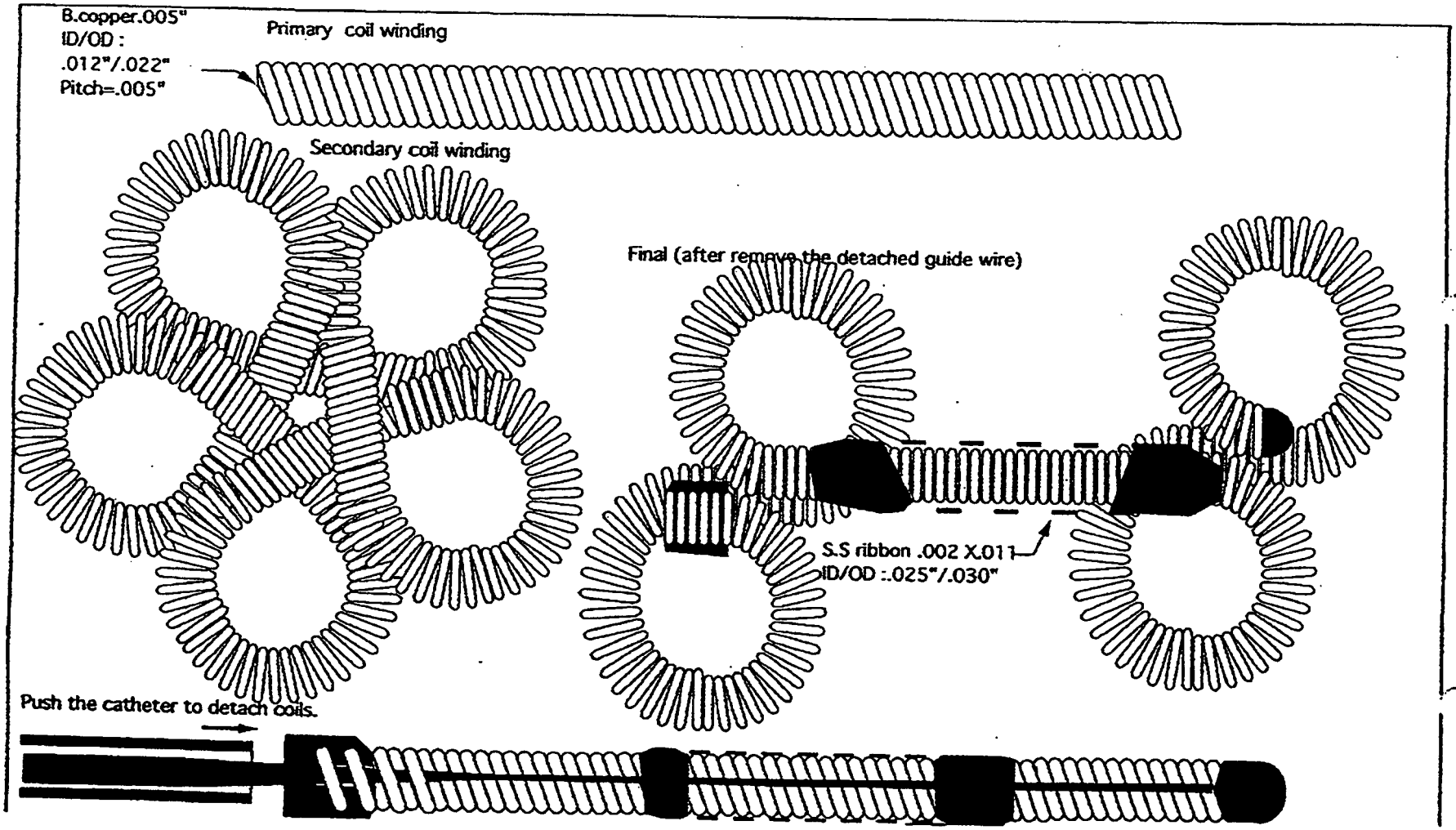
Street Address

City, State, Zip

Citizenship


B.copper.005"
ID/OD :
.015"/.025"
8cm
Pitch=.005"
2cm
Pitch= .010"
8cm
2 cm
8 cm
Secondary winding
Final (after remove the detached guide wire)
2.5cm
S.S ribbon .002 X.011
ID/OD :.025"/.030"
ROTATE COUNTERCLOCKWISE TO DETACHED IT

REDACTED


B.copper.005"
ID/OD :
.012"/.022"
Pitch=.005"
Primary coil winding
Secondary coil winding
Final (after remove the detached guide wire)
S.S ribbon .002 X.011
ID/OD :.025"/.030"
Push the catheter to detach coils.

REDACTED

EXHIBIT D

Conceptus

REDACTED

Date:

Invention Disclosure

Invention Disclosure #: 95003-2

Names of Inventors: Julian Nikolchev
Dai Ton
Amy Thurmond

INSTRUCTIONS: Please provide the information requested. Please sign this form and have your signature witnessed where noted. Submit this form to the Patent Coordinator.

Short Title of Invention: Transcervical Fallopian Tube Occlusion Devices and their Delivery.

I. Purpose

A novel device and method for delivery of fallopian tube occlusion devices which would provide permanent or reversible means of contraception.

The Invention:

a) Background (circumstances that led to the invention)

It is common knowledge that fertilization occurs in the fallopian tubes, where sperm and ovum meet. Thus it is believed that the most effective means for contraception would be by placing a device in the fallopian tube which would either prevent the sperm and ovum from ever encountering each other, or would prevent fertilization from occurring once they do meet.

IUD's are some of the most well known and most effective devices for contraception. While their function is not completely understood, it is known that IUD's combining copper are very effective in preventing undesirable pregnancies. IUD's, however, are also limited in their effectiveness due to unplanned expulsion or removal due to excessive pain or bleeding. Placing a device in each fallopian tube, which in addition can provide the active functionality of pregnancy prevention due to the use of copper materials would be very attractive and significantly improved method for reversible or permanent contraception.

REDACTED

II. Description

a) Describe invention (including the problem to be solved by the invention and the structure of the invention)

This invention provides a means to deliver novel fallopian tube devices into the isthmic (or beyond) portion of each tube. The devices may have several embodiments based on a general design of micro-coils. The delivery system involves uterine access device (such as a hysteroscope or uterine cannula that can be predictably and consistently placed at a close proximity or directly into each ostium of the fallopian tube), guidewire and fallopian tube catheter which can be used in conjunction to catheterize the fallopian tube to the desired location for placing the tubal devices, fallopian tube devices and pusher type device for delivering the tubal devices through the catheter.

Fallopian tube devices design: The devices consist of a small diameter metallic wire that has been shaped into a coil. This is it's initial shape. Consequently, this cylindrical coil can be shaped into various secondary shapes. The secondary shapes are created by using shaping fixture and appropriate heat treatment regiment. Additionally, the coils effectiveness may be improved by adding fibers to its structure. The coils are straightened out into their primary shape, forming a spring-like cylinder with O.D. smaller that the fallopian tube delivery catheter and inserted in the catheter. Using a pusher, they are pushed to the distal end of the catheter, which is placed inside the fallopian tube. As the coils emerge from the catheter, they try to form the secondary shape, which is designed to be larger than the inner lumen of the fallopian tube, thus applying a strong force against its walls. A combination of this force with the design of the secondary shape to maximize this force, prevents these coils to be expelled from the tube. If desired, adding fibers to the coils can be used to emphasize and build greater resistance to expulsion and greater copper volume per device, if the fiber is made from copper wire.

Coil materials:

1) basic coil can be made of several metals or metal alloys with good memory characteristics, such as stainless steel or platinum. If there is a desire to add the effect of copper, then the basic coil can be coated with pure copper layer, or a copper alloy, such as berillium/copper can be used as the basic material.

2) coil fibers can be made from several polymeric materials, such as rayon or dacron, or copper wire ≈ 0.001"-0.002" in O.D.

If there is a desire to reverse this procedure, the coil devices can be removed by using a "snare" type of device. This device can be placed in the fallopian tube to snare the coils and then pull them out.

If there is a desire to cause permanent contraception (or sterilization) in the tube, then once the Intrafallopian Tube Devices (IFD) have been placed in the tube, and just before removing the pusher device, which is still in contact with the IFD's, a small amount of current can be applied through the pusher to the IFD's, causing the fallopian tube tissue in contact with IFD's to be dessechated and thus attached to the IFD's. This action will likely cause permanent tubal damage, leading to the formation of scar tissue encapsulating the IFD and causing permanent occlusion of the tubal lumen.

REDACTED

II. **Description** (continued)
b) Invention Drawing:

Attached.

REDACTED

III. Chronological description of activities undertaken to make the invention. Please indicate who carried out each step and who witnessed each step. (Use separate sheet of paper if necessary.)

1. Discussed with Dai Ton and Amy Thurmond in
2. Device prototyped in · by Julian Nikolchev and Dai Ton at Conceptus.
3. Device tested in in-vitro models in and

REDACTED

If the invention is being used in a Conceptus' commercial process or product, give an estimate of first date of such use: _____

Used since:

In:

If the invention has been or will be disclosed outside the company, please recite the circumstances.

On:

If the invention has not been disclosed outside the company, please do not disclose it outside the company without prior agreement of patents coordinator.

INVENTORS:

REDACTED

(signature)

Julian Nikolchev
(printed name)

Street Address
251 DURAZNO WAY
Street Address
Portola Valley, CA 94028
City, State, Zip
Citizenship

(signature)

DAI TON
(printed name)

1693 FLICKINGER AVE
Street Address
SAN JOSE CA 95131
Street Address
City, State, Zip
US Citizen
Citizenship

(signature)

(printed name)

(date)

Street Address
Street Address
City, State, Zip
Citizenship

(signature)

(printed name)

(date)

Street Address
Street Address
City, State, Zip
Citizenship

(signature)

(printed name)

(date)

Street Address
Street Address
City, State, Zip
Citizenship

(signature)

(printed name)

(date)

Street Address
Street Address
City, Sate, Zip
Citizenship

REDACTED

WITNESSES:

Charles Mills
(signature)

Charles Mills
(printed name)

(date)

(signature)

(printed name)

(date)

32407 Monterey Dr
Street Address

Union City CA 94587
Street Address

City, State, Zip

Citizenship

Street Address

Street Address

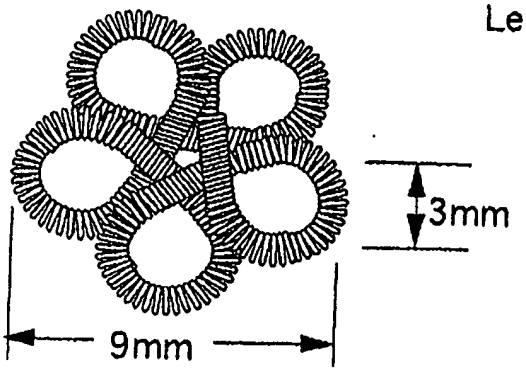
City, State, Zip

Citizenship

REDACTED

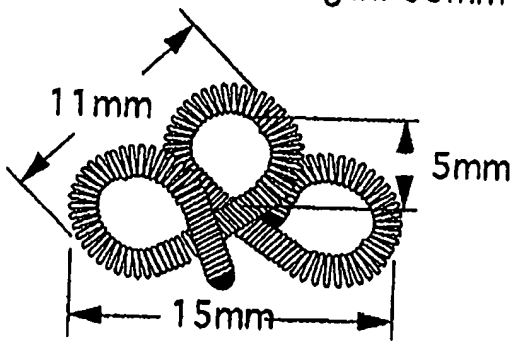
Flower coils: 3x 65mm

Length: 65mm



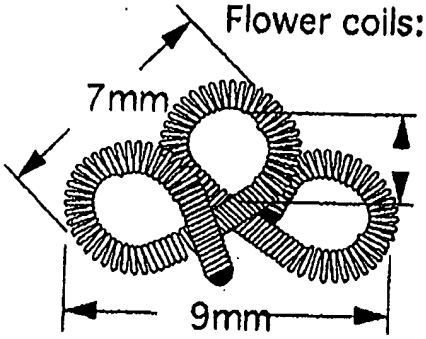
Flower coils: 5x 55mm

Length: 55mm



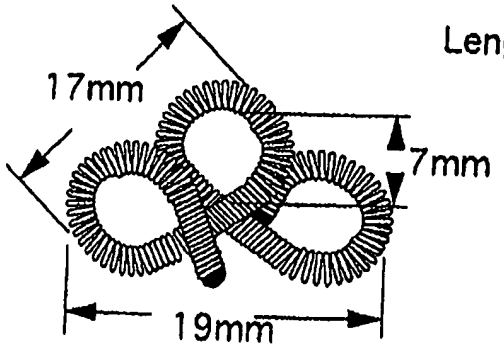
Flower coils: 3x 30mm

Length: 30mm

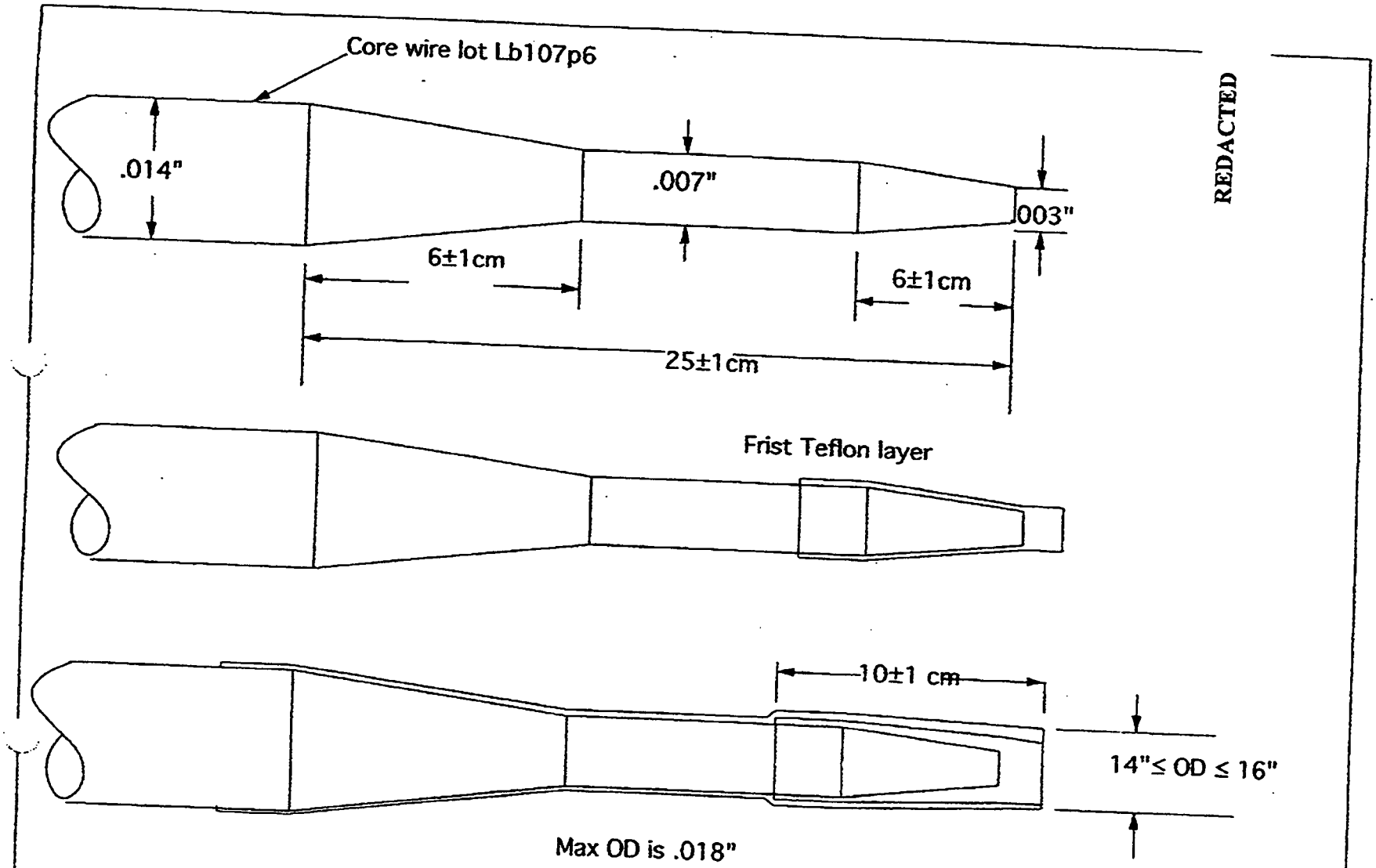


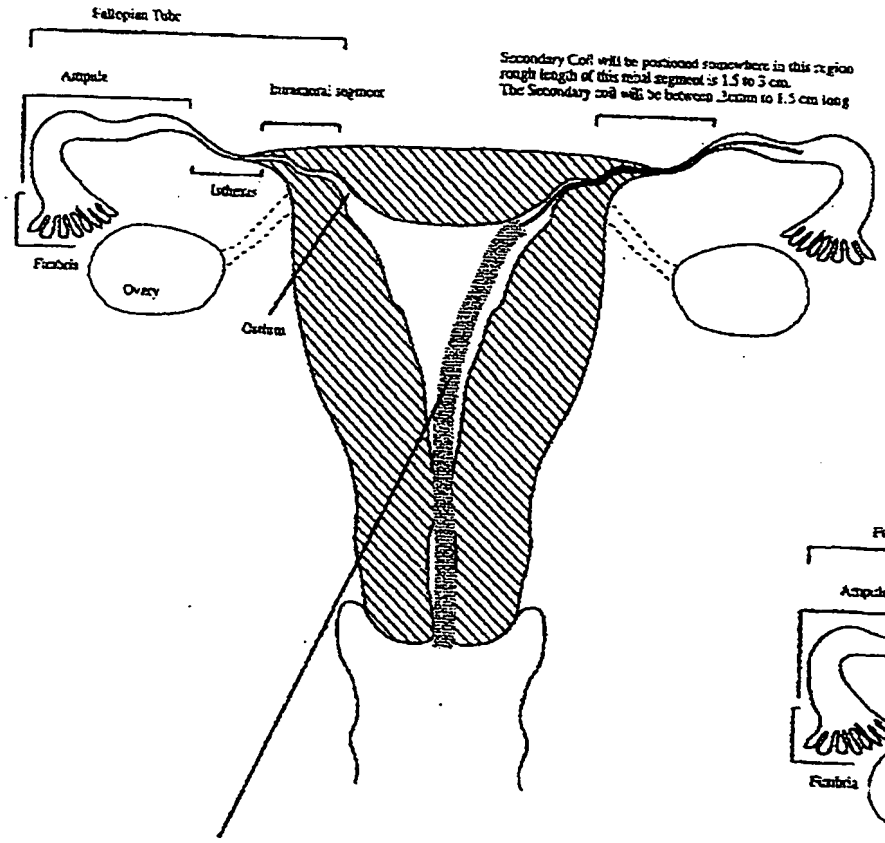
Flower coils: 7x 75mm

Length: 75mm

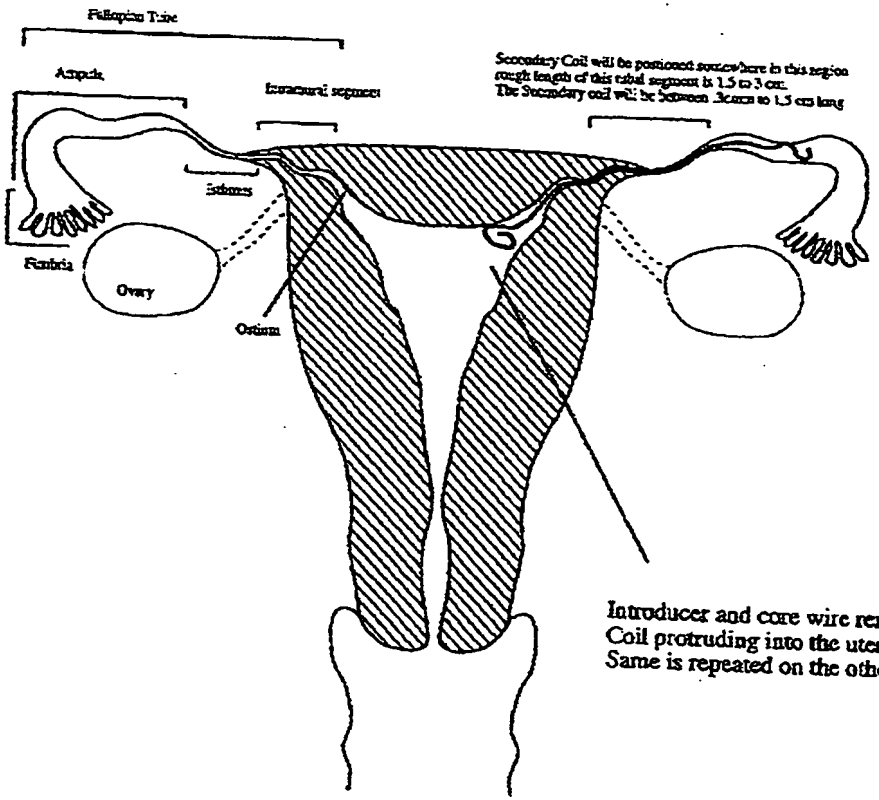


Material: Beryllium copper


Core wire lot Lb107p6
.014"
.007"
003"
6±1cm
6±1cm
25±1cm
Frist Teflon layer
10±1 cm
14"≤ OD ≤ 16"
Max OD is .018"
REDACTED
Conceptus, inc
Date:
Approve by:
Finish:
Revise:
Designed & drew by: Dai Ton
Scale: Not draw to scale.
Pusher .018"



Uterine introducer cannula
(or could be a hysteroscope



Introducer and core wire removed
Coil protruding into the uterus
Same is repeated on the other side.

Conceptus

Tubouschon Coil Selective Tubal Occlusion Product (S/TOP)
CONFIDENTIAL

REDACTED

EXHIBIT E

REDACTED

LAW OFFICES
TOWNSEND AND TOWNSEND KHOURIE AND CREW
PATENTS, TRADEMARKS, COPYRIGHTS, ANTITRUST, COMMERCIAL LITIGATION

SAN FRANCISCO OFFICE
ONE MARKET PLAZA
SAN FRANCISCO, CA 94105
(415) 543-9600

379 LYTTON AVENUE
PALO ALTO, CA 94301-1431
PHONE (415) 326-2400
FAX (415) 326-2422

SEATTLE OFFICE
601 UNION STREET
SEATTLE, WA 98101
(206) 467-9600

April 29, 1995

via FACSIMILE: 415/802-7272

Julian Nikolchev, Vice-President
New Product Development and Operations
CONCEPTUS, INC.
1021 Howard Avenue
San Carlos, CA 94070

Re: New Application Files
Our File: 16355-0000

Dear Julian:

The following is a list of the new disclosures TTKC has received from Conceptus over the past month. The list includes your docket no., the corresponding TTKC docket no., and the status of the case.

Conceptus No.	TTKC No.	Status
95003-1	[redacted]	TTKC to prepare draft application.
95003-2	16355-24	TTKC to prepare draft application.

Please call if you have any questions.

Very truly yours,

James M. Heslin /KK

James M. Heslin

TMH:vv

EXHIBIT F

REDACTED

LAW OFFICES
TOWNSEND AND TOWNSEND KHOURIE AND CREW
PATENTS, TRADEMARKS, COPYRIGHTS, ANTITRUST, COMMERCIAL LITIGATION

SAN FRANCISCO OFFICE
ONE MARKET PLAZA
SAN FRANCISCO, CA 94105
(415) 543-9600

379 LYTTON AVENUE
PALO ALTO, CA 94301-1431
PHONE (415) 326-2400
FAX (415) 326-2422

SEATTLE OFFICE
601 UNION STREET
SEATTLE, WA 98101
(206) 467-9600

June 1, 1995

via Federal Express

Mr. Julian Nikolchev
Conceptus, Inc.
1021 Howard Avenue
San Carlos, CA 94070

Re: New U.S. Patent Applications for
CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND THEIR DELIVERY
Your File 95003-2 / Our File 16355-24

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES HAVING MECHANICAL FALLOPIAN TUBE ATTACHMENT
Your File 95003-1 / Our File 16355-25

Dear Julian:

Enclosed for your review are draft patent applications for your Contraceptive Intrafallopian Device and your Contraceptive Intrafallopian Device Having a Helical Outer Winding.

Due to upcoming changes in the patent laws, it would be preferable if we could file these applications by June 7, 1995. It would therefore be best if we have any comments or changes from you in time to incorporate them and file these applications by that date.

Please contact Mark Barrish, who prepared the drafts, or me if you have any questions.

Very truly yours,

James M. Heslin

JMH/MDB/gs
Enclosures

EXHIBIT G

REDACTED

LAW OFFICES
TOWNSEND AND TOWNSEND KHOURIE AND CREW
PATENTS, TRADEMARKS, COPYRIGHTS, ANTITRUST, COMMERCIAL LITIGATION

SAN FRANCISCO OFFICE
ONE MARKET PLAZA
SAN FRANCISCO, CA 94105
(415) 543-9600

379 LYTTON AVENUE
PALO ALTO, CA 94301-1431
PHONE (415) 326-2400
FAX (415) 326-2422

SEATTLE OFFICE
601 UNION STREET
SEATTLE, WA 98101
(206) 467-9600

June 6, 1995

via Aero Special Delivery

Mr. Julian Nikolchev
Conceptus, Inc.
1021 Howard Avenue
San Carlos, CA 94070

Re: New U.S. Patent Applications for
CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND THEIR DELIVERY
Your File 95003-2 / Our File 16355-24

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES HAVING MECHANICAL FALLOPIAN TUBE ATTACHMENT
Your File 95003-1 / Our File 16355-25

Dear Julian:

Enclosed for your review are the patent applications for the Intrafallopian Device and for the Intrafallopian Device Having a Helical Surface.

Very truly yours,

Mark D. Barrish

MDB/gs
Enclosures